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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2022

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____to_____.

Commission File Number 001-40366

WEREWOLF THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**82-3523180**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1030 Massachusetts Avenue, Suite 210	
Cambridge, Massachusetts	**02138**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 952-0555

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	HOWL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company.

See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 6, 2022, there were 27,654,248 shares of common stock, $0.0001 par value per share, outstanding.

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References to Werewolf

Throughout this Quarterly Report on Form 10-Q, or Quarterly Report, the "Company," "Werewolf," "Werewolf Therapeutics," "we," "us," "our," and similar references, except where the context requires otherwise, refer to Werewolf Therapeutics, Inc. and its consolidated subsidiary, and "board of directors" refers to the board of directors of Werewolf Therapeutics, Inc.

Cautionary Note Regarding Forward-Looking Statements and Industry Data

This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements.

The words "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goal," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will," "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs and preclinical studies and planned clinical trials, including the anticipated timing of submission of investigational new drug applications;
- our estimates regarding expenses, capital requirements, need for additional financing and the period over which we believe our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- our plans to develop and, if approved, subsequently commercialize product candidates;
- the timing of and our ability to submit applications and obtain and maintain regulatory approvals for product candidates;
- the potential advantages of our PREDATOR platform and our ability to use our platform to identify and develop future product candidates;
- our estimates regarding the potential market opportunities for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the impact of government laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- developments and expectations regarding developments and projections relating to our competitors and our industry;
- the impact of the COVID-19 pandemic on our business, including our preclinical studies and clinical trials; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart our Business Startup Act of 2012.

There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report, particularly in Part II, Item 1A. "Risk Factors", that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report and the documents that we have filed or incorporated by reference as exhibits to this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report are made as of the date of this Quarterly Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements.

Trademarks and Trade names

We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. The service marks and trademarks that we own include the marks PREDATOR™ and INDUKINE™. Other trademarks, service marks and trade names appearing in this Quarterly Report are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Quarterly Report are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

Risk Factor Summary

Our business is subject to numerous risks that, if realized, could materially and adversely affect our business, financial condition, results of operations and future growth prospects. These risks are discussed more fully in Part II, Item 1A. "Risk Factors" in this Quarterly Report. These risks include, but are not limited to, the following:

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.
- We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will need to obtain substantial additional funding to finance our operations and complete the development and any commercialization of WTX-124, WTX-330 and any future product candidates.
- We are early in our development efforts and our current product candidates will require successful completion of additional preclinical and clinical development before we can seek regulatory approval for any product candidates.
- Our business is highly dependent on the success of our initial INDUKINE molecules, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and launch a product commercially.
- Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any products of commercial value.
- Manufacturing INDUKINE molecules is subject to risk since they are a novel class of multi-domain biologics that include protease cleavable linkers, and they have never been produced on a clinical or commercial scale. We may be unable to manufacture INDUKINE molecules at the scale needed for clinical development and commercial production on a timely basis or at all.
- Preclinical studies and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes.
- We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We expect to develop WTX-124 and WTX-330, and potentially future product candidates, in combination with third-party drugs, some of which may still be in development, and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such drugs.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any product candidates.
- The manufacturing of biologics is complex and we do not have our own clinical manufacturing capabilities. We will rely on third parties to produce preclinical, clinical and commercial supplies of all current and any future product candidates.
- We rely on our license agreement with Harpoon Therapeutics, Inc. for patent rights with respect to our product candidates and may in the future acquire additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses.
- Our proprietary position in part depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.
- In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Werewolf Therapeutics, Inc.
Condensed Consolidated Balance Sheets (unaudited)
(amounts in thousands, except par value amounts)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 143,711	$ 157,531
Prepaid expenses and other current assets	1,725	3,537
Total current assets	145,436	161,068
Property and equipment, net	6,141	2,913
Restricted cash	1,208	1,208
Operating lease right of use asset	11,204	13,412
Other non-current assets	642	649
Total assets	$ 164,631	$ 179,250
Liabilities and Stockholders' Equity:		
Current liabilities:		
Accounts payable	$ 1,381	$ 2,037
Accrued expenses and other current liabilities	8,189	8,765
Operating lease liability, current	1,458	1,072
Total current liabilities	11,028	11,874
Operating lease liability, net of current portion	14,285	14,589
Total liabilities	25,313	26,463
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000 shares authorized at March 31, 2022 and December 31, 2021; no shares issued or outstanding as of March 31, 2022 or December 31, 2021	—	—
Common stock, $0.0001 par value, 200,000 shares authorized as of March 31, 2022 and December 31, 2021; 27,654 and 27,608 shares issued as of March 31, 2022 and December 31, 2021, respectively; 27,420 and 27,313 shares outstanding as of March 31, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	407,554	405,680
Accumulated deficit	(268,238)	(252,895)
Total stockholders' equity	139,318	152,787
Total liabilities and stockholders' equity	$ 164,631	$ 179,250

The accompanying notes are an integral part of these condensed consolidated financial statements.

Werewolf Therapeutics, Inc.
Condensed Consolidated Statements of Operations (unaudited)
(amounts in thousands, except per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 10,945	$ 4,817
General and administrative	4,421	2,635
Total operating expenses	15,366	7,452
Operating loss	(15,366)	(7,452)
Other income:		
Interest income, net	23	17
Total other income	23	17
Net loss	(15,343)	(7,435)
Accretion of redeemable convertible preferred stock to redemption value	—	(95,016)
Net loss attributable to common stockholders	$ (15,343)	$ (102,451)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.56)	$ (83.36)
Weighted-average common shares outstanding, basic and diluted	27,393	1,229

The accompanying notes are an integral part of these condensed consolidated financial statements.

Werewolf Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (unaudited)
(amounts in thousands)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders'Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	—	$ —	—	$ —	27,608	$ 2	$ 405,680	$ (252,895)	$ 152,787
Stock-based compensation expense	—	—	—	—	—	—	1,745	—	1,745
Stock option exercises	—	—	—	—	46	—	129	—	129
Net loss	—	—	—	—	—	—	—	(15,343)	(15,343)
Balance at March 31, 2022	—	$ —	—	$ —	27,654	$ 2	$ 407,554	$ (268,238)	$ 139,318

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	80,247	$ 69,012	78,222	$ 72,070	1,746	$ 2	$ —	$ (51,865)	$ (51,863)
Stock-based compensation expense	—	—	—	—	—	—	539	—	539
Stock option exercises	—	—	—	—	14	—	21	—	21
Accretion of redeemable convertible preferred stock to redemption value	—	49,753	—	45,263	—	—	(560)	(94,456)	(95,016)
Net loss	—	—	—	—	—	—	—	(7,435)	(7,435)
Balance at March 31, 2021	80,247	$ 118,765	78,222	$ 117,333	1,760	$ 2	$ —	$ (153,756)	$ (153,754)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Werewolf Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows (unaudited)
(amounts in thousands)

	Three Months Ended March 31,	
	2022	**2021**
Operating activities:		
Net loss	$ (15,343)	$ (7,435)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,745	539
Depreciation expense	98	39
Non-cash lease expense	383	166
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,789	81
Accounts payable	(674)	724
Accrued expenses and other current liabilities	(2,031)	(1,331)
Right of use assets and operating lease liability	82	(159)
Other liabilities	—	50
Net cash used in operating activities	(13,951)	(7,326)
Investing activities:		
Purchases of property and equipment	(28)	(13)
Net cash used in investing activities	(28)	(13)
Financing activities:		
Deferred financing costs	—	(559)
Proceeds from stock option exercises	159	21
Net cash provided by (used in) financing activities	159	(538)
Net decrease in cash and cash equivalents	(13,820)	(7,877)
Cash, cash equivalents and restricted cash—beginning of period	158,830	92,777
Cash, cash equivalents and restricted cash—end of period	$ 145,010	$ 84,900
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 1,552	$ 130
Stock option exercise receivables in prepaid expenses and other current assets	$ (30)	$ —
Non-cash accretion of Series A and Series B redeemable convertible preferred stock	$ —	$ 95,016
Issuance costs in accounts payable and accrued expenses	$ —	$ 560

The accompanying notes are an integral part of these condensed consolidated financial statements.

Werewolf Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of Business

Werewolf Therapeutics, Inc. ("Werewolf" or the "Company") was incorporated in the state of Delaware in October 2017. The Company is an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer. The Company's headquarters are located in Cambridge, Massachusetts.

Since inception, the Company has devoted substantially all of its time and efforts to performing research and development activities, raising capital and recruiting management and technical staff to support these operations. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The Company had cash and cash equivalents of $143.7 million at March 31, 2022. The Company expects that its cash and cash equivalents will enable it to fund its operating expenses and capital expenditure requirements for at least twelve months from the filing date of this Quarterly Report. However, additional funding will be necessary beyond this point to fund future preclinical and clinical activities. The Company expects to finance its future cash needs through a combination of equity or debt financings, collaboration agreements, strategic alliances and licensing arrangements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements as of March 31, 2022 and December 31, 2021, and for the three months ended March 31, 2022 and 2021, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and generally accepted accounting principles in the United States of America ("GAAP") as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB") for condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all normal recurring adjustments which are necessary for a fair presentation of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC (the "Annual Report").

The information presented in the condensed consolidated financial statements and related notes as of March 31, 2022, and for the three months ended March 31, 2022 and 2021, is unaudited. The December 31, 2021 condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three months ended March 31, 2022 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2022, or any future period.

The accompanying condensed consolidated financial statements include the accounts of Werewolf Therapeutics, Inc. and its wholly-owned subsidiary, Werewolf Therapeutics Mass Securities, Inc. All intercompany transactions and balances have been eliminated in consolidation.

Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2021, and the notes thereto, which are included in the Annual Report. There have been no material changes in the Company's significant accounting policies during the three months ended March 31, 2022.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates which include, but are not limited to, the fair values of common stock and redeemable convertible preferred stock, and the fair value of the preferred stock tranche rights. Actual results could differ from those estimates.

Recent Accounting Pronouncements

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's condensed consolidated financial statements upon adoption.

Subsequent Events

The Company has evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were issued. Other than as described in these financial statements, the Company did not identify any subsequent events that would have required adjustment to or disclosure in the financial statements.

3. Financial Instruments and Fair Value Measurements

Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value is determined based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect certain market assumptions. As a basis for considering such assumptions, GAAP establishes a three-tier value hierarchy, which prioritizes the inputs used to develop the assumptions and for measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets for identical assets; (Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and (Level 3) unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities.

The carrying amounts reflected in the condensed consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Assets measured at fair value on a recurring basis as of March 31, 2022 were as follows (in thousands):

	Quoted Price in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 143,711	$ —	$ —	$ 143,711
Total assets	$ 143,711	$ —	$ —	$ 143,711

Assets measured at fair value on a recurring basis as of December 31, 2021 were as follows (in thousands):

	Quoted Price in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 157,531	$ —	$ —	$ 157,531
Total assets	$ 157,531	$ —	$ —	$ 157,531

There were no changes in valuation techniques during the three months ended March 31, 2022. There were no liabilities measured at fair value on a recurring basis as of March 31, 2022 or December 31, 2021.

4. Restricted Cash

The Company maintained restricted cash of $1.3 million at each of March 31, 2022 and December 31, 2021. At each of March 31, 2022 and December 31, 2021, $0.1 million of the Company's restricted cash balance is included within "Prepaid expenses and other current assets" in the accompanying condensed consolidated balance sheets. These amounts are comprised solely of letters of credit required pursuant to the Company's leased office spaces.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of March 31, 2022 and December 31, 2021 were comprised as follows (in thousands):

	March 31, 2022	December 31, 2021
Manufacturing	$ 2,700	$ 3,427
Contract research	1,940	2,542
Leasehold improvements	1,455	—
Employee compensation and benefits	1,148	2,200
Professional fees	816	433
Other	130	163
Total accrued expenses and other current liabilities	$ 8,189	$ 8,765

6. Common and Preferred Stock

Common Stock

The Company is authorized to issue 200.0 million shares of common stock. Common stockholders are entitled to dividends if and when declared by the Company's board of directors. As of March 31, 2022, no dividends on common stock had been declared by the Company.

The Company had reserved shares of common stock for issuance as follows (in thousands):

	As of March 31, 2022	As of December 31, 2021
Options issued and outstanding	4,133	3,266
Warrants issued and outstanding	59	59
Total	4,192	3,325

Preferred Stock

The Company is authorized to issue 5.0 million shares of undesignated preferred stock in one or more series. As of March 31, 2022, no shares of preferred stock were issued or outstanding.

7. Stock-based Compensation

2017 Stock Incentive Plan

In December 2017, the Company adopted the 2017 Stock Incentive Plan (the "2017 Plan"), as amended and restated, under which it could grant incentive stock options ("ISOs"), non-qualified stock options, restricted stock awards ("RSAs"), restricted stock units ("RSUs"), stock appreciation rights and other stock-based awards to eligible employees, officers, directors and consultants. The terms of stock options and RSAs, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2017 Plan.

2021 Stock Incentive Plan

In April 2021, the board of directors adopted and the Company's stockholders approved the 2021 Stock Incentive Plan (the "2021 Plan"), which became effective immediately prior to the effectiveness of the Company's initial public offering ("IPO"). As a result of the adoption of the 2021 Plan, no further awards will be made under the 2017 Plan.

The 2021 Plan provides for the grant of ISOs, non-qualified stock options, RSAs, RSUs, stock appreciation rights and other stock-based awards. The Company's employees, officers, directors, consultants and advisors are eligible to receive awards under the 2021 Plan. The terms of awards, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2021 Plan.

The Company initially registered 3,352,725 shares of common stock under the 2021 Plan, pursuant to a Registration Statement on Form S-8 filed with the SEC on April 30, 2021, which was comprised of (i) 2,843,116 shares of common stock reserved for issuance under the 2021 Plan, (ii) 31,884 shares of common stock originally reserved for issuance under the 2017 Plan that became available for issuance under the 2021 Plan upon the completion of the IPO, and (iii) 477,725 shares of unvested restricted stock subject to repurchase by us that may become issuable under the 2021 Stock Incentive Plan following such repurchase. The 2021 Plan also provides that an additional number of shares will be added annually to the shares authorized for issuance under the 2021 Plan on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022 and continuing until, and including, the fiscal year ended December 31, 2031. The number of shares added each year will be equal to the lesser of (i) 5% of the number of outstanding common stock on such date and (ii) such amount as determined by the board of directors. Effective January 1, 2022, 1,380,397 additional shares were automatically added to the shares reserved for issuance under the 2021 Plan pursuant to this evergreen provision.

As of March 31, 2022, there were 2,406,657 shares available for future issuance under the 2021 Plan.

2021 Employee Stock Purchase Plan

In April 2021, the board of directors adopted and the Company's stockholders approved the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective immediately prior to the effectiveness of the IPO. The Company initially reserved 244,000 shares of common stock for future issuance under the 2021 ESPP. The 2021 ESPP provides that an additional number of shares will automatically be added to the shares reserved for issuance on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022 and continuing for each fiscal year until, and including, the fiscal year ending on December 31, 2032. The number of shares added each year will be equal to the lowest of (i) 488,000 shares of common stock, (ii) 1% of the number of shares of outstanding common stock on such date, and (iii) such amount as determined by the board of directors. The company had not initiated any offering periods under the 2021 ESPP as of March 31, 2022, and no shares were added on January 1, 2022, pursuant to the evergreen provision.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized in the condensed consolidated statements of operations for the three months ended March 31, 2022 and 2021 was as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 781	$ 140
General and administrative	964	399
Total stock-based compensation	$ 1,745	$ 539

Restricted Stock Activity

The Company may, at its discretion, repurchase unvested shares of restricted stock issued pursuant to the 2017 Plan at the initial purchase price if the employees or non-employees terminate their service relationship with the Company. The shares are recorded in stockholders' equity as they vest.

The following table summarizes restricted stock award activity during the three months ended March 31, 2022 (in thousands, except per share amounts):

	Shares/Units	Weighted-Average Grant Date Fair Value Per Share
Unvested at December 31, 2021	295	$ 1.35
Granted	—	$ —
Vested	(61)	$ 1.33
Forfeited	—	$ —
Unvested at March 31, 2022	234	$ 1.36

As of March 31, 2022, there was unrecognized stock-based compensation expense related to unvested restricted stock awards of $0.3 million, which the Company expects to recognize over a weighted-average period of approximately 1.1 years.

The aggregate fair value of restricted stock awards that vested during the three months ended March 31, 2022 and 2021, based upon the fair values of the stock underlying the restricted stock awards on the day of vesting, was $0.5 million and $0.3 million, respectively.

Stock Option Activity

The fair value of stock options granted during the three months ended March 31, 2022 and 2021 was calculated on the date of grant using the following weighted-average assumptions:

	Three Months Ended March 31,	
	2022	2021
Risk-free interest rate	1.6 %	0.8 %
Expected term (in years)	6.0	6.0
Dividend yield	— %	— %
Expected volatility	76.0 %	79.8 %

Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the three months ended March 31, 2022 and 2021 was $7.54 and $4.23 per share, respectively.

The following table summarizes stock option activity during the three months ended March 31, 2022 (in thousands, except per share amounts):

	Options Outstanding		
	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2021	3,266	$ 8.24	9.02
Granted	928	$ 11.34	
Exercised	(46)	$ 2.83	
Cancelled	(15)	$ 7.69	
Outstanding at March 31, 2022	4,133	$ 9.00	9.00
Exercisable at March 31, 2022	818	$ 5.73	8.65

The aggregate intrinsic fair value of stock options exercised during the three months ended March 31, 2022 and 2021 was $0.3 million and $0.1 million, respectively.

As of March 31, 2022, there was unrecognized stock-based compensation expense related to unvested stock options of $20.0 million, which the Company expects to recognize over a weighted-average period of approximately 2.9 years.

8. Net Loss Attributable to Common Stockholders per Share

For purposes of the diluted net loss attributable to common stockholders per share calculation, redeemable convertible preferred stock, outstanding stock options, unvested restricted stock awards and warrants to purchase common stock are considered to be potentially dilutive securities, however the following weighted-average amounts were excluded from the calculation of diluted net loss attributable to common stockholders per share because their effect would be anti-dilutive (in thousands):

	March 31,	
	2022	2021
Redeemable convertible preferred stock (as converted)	—	18,280
Outstanding stock options	4,133	2,401
Unvested restricted common stock	234	498
Warrants to purchase common stock	59	59
Total	4,426	21,238

9. Subsequent Events

Jazz Collaboration

On April 6, 2022, the Company entered into a Collaboration and License Agreement (the "Collaboration Agreement") with Jazz Pharmaceuticals Ireland Limited ("Jazz") pursuant to which the Company granted Jazz certain licenses to develop and commercialize products containing the Company's Interferon alpha ("IFNα") INDUKINE™ molecule, WTX-613, as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria (each such product, a "Licensed Product"). Under the Collaboration Agreement, the Company will initially be responsible for certain pre-clinical development activities with respect to WTX-613 and other development activities specified in mutually agreed upon development plans. Jazz will generally reimburse the Company for the cost of such activities. Jazz will be responsible for all other development and commercialization activities conducted to exploit the Licensed Products, including submission of an investigational new drug application ("IND") to the U.S. Food and Drug Administration (the "FDA").

Under the terms of the Collaboration Agreement, the Company received an upfront payment of $15.0 million in April 2022. The Company is eligible to receive up to $520.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products. In addition, the Company is eligible to receive tiered mid-single digit royalties based on Jazz's, and any of its affiliates' and sublicensees' annual net sales of Licensed Products, subject to reduction in specified circumstances.

Pacific Western Bank Loan Facility

On April 12, 2022 (the "Closing Date"), the Company entered into an Amended and Restated Loan and Security Agreement (the "Loan Agreement") with Pacific Western Bank ("PWB"), which amended and restated in its entirety that certain Loan and Security Agreement dated May 29, 2020, as subsequently amended on December 22, 2020 and February 18, 2021, between the Company and PWB, which had expired on November 29, 2021 as a result of the Company's decision not to draw down any term loans by such date. Under the terms of the Loan Agreement, PWB made available term loans in an aggregate principal amount of up to $40.0 million (the "Term Loans"), consisting of (i) a term loan in the aggregate principal amount of up to $20.0 million available at any time after the Closing Date until February 28, 2024, as extended to August 31, 2024 upon the satisfaction of certain conditions set forth in the Loan Agreement (such date, the "Amortization Date"), and (ii) a term loan in the aggregate principal amount of up to $20.0 million available at any time after the Closing Date until the Amortization Date upon the acceptance by the FDA of two IND submissions on or before March 31, 2023. As of May 10, 2022, the Term Loans remain undrawn.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis is meant to provide material information relevant to an assessment of the financial condition and results of operations of our company, including an evaluation of the amounts and uncertainties of cash flows from operations and from outside resources, so as to allow investors to better view our company from management's perspective. The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our Annual Report on Form 10-K for the year ended December 31, 2021, or the Annual Report on Form 10-K, that was filed with the United States Securities and Exchange Commission, or SEC, on March 24, 2022. *In addition to historical information, the discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors we believe could cause or contribute to these differences below and elsewhere in this Quarterly Report, including those factors set forth in the section entitled "Cautionary Note Regarding Forward-Looking Statements and Industry Data" and in the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report. You should carefully read the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report.*

Overview

We are an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer. We are leveraging our proprietary PREDATOR platform to design conditionally activated molecules that stimulate both adaptive and innate immunity with the goal of addressing the limitations of conventional proinflammatory immune therapies. Our molecules, which we refer to as INDUKINE molecules, are intended to activate selectively in the tumor microenvironment. Our most advanced product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2 and Interleukin-12, respectively, INDUKINE molecules for the treatment of multiple tumor types. We remain on track as we advance towards clinical development for WTX-124 and WTX-330.

In April 2022, we entered into a Collaboration and License Agreement, or the Collaboration Agreement, with Jazz Pharmaceuticals Ireland Limited, or Jazz, pursuant to which we granted Jazz certain licenses to develop and commercialize products containing our Interferon alpha (IFNα) INDUKINE molecule, WTX-613, as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria (each such product, a "Licensed Product"). Under the Collaboration Agreement, we will initially be responsible for certain pre-clinical development activities with respect to WTX-613 and other development activities specified in mutually agreed upon development plans. Jazz will generally reimburse us for the cost of such activities. Jazz will be responsible for all other development and commercialization activities conducted to exploit the Licensed Products, including submission of an IND to the FDA. Under the terms of the Collaboration Agreement, we received an upfront payment of $15.0 million in April 2022. We are also eligible to receive up to $520.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products. In addition, we are eligible to receive tiered mid-single digit royalties based on Jazz's, and any of its affiliates' and sublicensees', annual net sales of Licensed Products, subject to reduction in specified circumstances.

We were incorporated and commenced operations in 2017. Since inception, we have devoted substantially all of our time and efforts to performing research and development activities, raising capital and recruiting management and technical staff to support these operations. To date, we have financed our operations primarily with proceeds from the sales of our convertible promissory notes and equity securities. From December 2017 to August 2018, we issued convertible promissory notes for aggregate gross cash proceeds of $11.0 million. From August 2019 to June 2020, we issued an aggregate of 80,246,565 shares of Series A preferred stock for aggregate gross cash proceeds of $44.2 million, together with conversion of all of our previously issued convertible promissory notes. In December 2020, we issued 78,222,173 shares of Series B preferred stock at a price of $0.92 per share, resulting in gross cash proceeds of $72.1 million. On May 4, 2021, we completed our initial public offering, or IPO, pursuant to which we issued and sold 7,500,000 shares of our common stock at a public offering price of $16.00 per share. We received net proceeds of approximately $109.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Due to our significant research and development expenditures, we have accumulated substantial net losses since our inception. As of March 31, 2022, we had an accumulated deficit of $268.2 million. We expect to continue to incur substantial and increasing expenses and net losses for the foreseeable future, as we continue to advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to raise capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations.

Impact of COVID-19 on Our Business

The worldwide COVID-19 pandemic continues to evolve, and we will continue to monitor the COVID-19 pandemic closely. To date, we have not experienced a material financial statement impact or material business disruptions, including with our vendors, or impairments of any of our assets as a result of the pandemic. However, we cannot, at this time, predict the specific extent, duration or full impact that the COVID-19 pandemic will have on our financial statements and operations, including our ongoing and planned preclinical activities and future clinical trials. The extent of the impact of the COVID-19 pandemic, including the emergence of new variants or subvariants of the virus, on our business, operations and clinical development timelines and plans remains uncertain and will depend on certain developments, including the duration and spread of the pandemic and its impact on our contract research organizations, or CROs, third-party manufacturers, and other third parties with which we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. To the extent possible, we are conducting business as usual. We will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with which we do business.

Furthermore, the COVID-19 pandemic could affect our employees or the employees of research sites and service providers on which we rely, including CROs, as well as those of companies with which we do business, including our suppliers and contract manufacturing organizations, thereby disrupting our business operations. Quarantines and travel restrictions imposed by governments in the jurisdictions in which we and the companies with which we do business operate could materially impact the ability of employees to access preclinical and clinical sites, laboratories, manufacturing site and office. These and other events resulting from the COVID-19 pandemic could disrupt, delay, or otherwise adversely impact our business. Further information relating to the risks and uncertainties related to the ongoing COVID-19 pandemic is contained in the section titled “Risk Factors” in Part II, Item 1A of this Quarterly Report.

Financial Operations Overview

Revenue

Through March 31, 2022, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. As a result of our entry into the Collaboration Agreement, we expect to recognize collaboration revenue as a result of the receipt of the upfront payment, and any milestone payments that we receive under the Collaboration Agreement.

For the foreseeable future, we expect substantially all of our revenue will be generated from our Collaboration Agreement and any other collaborations or agreements that we may enter into.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties that conduct research and preclinical activities on our behalf;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and future clinical trial materials; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in our condensed consolidated financial statements as prepaid or accrued research and development expenses.

We typically use our employee and infrastructure resources across our development programs. We track external development costs by product candidate or development program, but we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates.

Our external development costs for the three months ended March 31, 2022 and 2021 were as follows:

	Three Months Ended March 31,	
	2022	2021
WTX-124	$ 2,231	$ 604
WTX-330	2,133	1,400
WTX-613	1,002	508
Pre-development candidates	477	152
Total external development costs	$ 5,843	$ 2,664

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we initiate clinical trials of WTX-124 and WTX-330 and continue to discover and develop additional product candidates. As a result of our entry into the Collaboration Agreement, commencing in April 2022, our external preclinical development costs for WTX-613 will generally be reimbursed by Jazz.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. The actual probability of success for our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expenses of our ongoing research activities as well as any preclinical studies and clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates and we may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development activities.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued research and development activities, manufacturing activities and expansion of our operations in connection with our anticipated commencement of clinical trials. We also anticipate increased expenses associated with operating as a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the SEC and listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums and investor relations costs.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,		
(in thousands)	**2022**	**2021**	**$ Change**
Operating expenses:			
Research and development	$ 10,945	$ 4,817	$ 6,128
General and administrative	4,421	2,635	1,786
Total operating expenses	15,366	7,452	7,914
Operating loss	(15,366)	(7,452)	(7,914)
Other income:			
Interest income, net	23	17	6
Total other income	23	17	6
Net loss	$ (15,343)	$ (7,435)	$ (7,908)

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,		
(in thousands)	**2022**	**2021**	**$ Change**
Manufacturing	$ 3,858	$ 1,988	$ 1,870
Personnel	3,304	1,446	1,858
Contract research organization	1,985	676	1,309
Facilities	806	137	669
Lab consumables	891	558	333
Other	101	12	89
Total research and development expenses	$ 10,945	$ 4,817	$ 6,128

Research and development expenses for the three months ended March 31, 2022 were $10.9 million, compared to $4.8 million for the three months ended March 31, 2021. The increase of approximately $6.1 million was primarily due to:

- $1.9 million of increased manufacturing expense related to costs incurred with contract manufacturing organizations to support the production of preclinical and future clinical trial materials associated with our product candidates WTX-124, WTX-330 and WTX-613;
- $1.9 million of increased personnel costs, including $0.7 million of increased stock-based compensation expense, primarily due to increased headcount associated with expanded discovery efforts as well as the hiring of a clinical development team;
- $1.3 million of increased contract research organization expense, primarily driven by preclinical studies to support IND enabling studies for WTX-124 and WTX-330; and
- $0.7 million of increased facilities expense, primarily driven by our operating lease for our future headquarters entered in May 2021 and our short-term lease that commenced in April 2021.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,		
(in thousands)	**2022**	**2021**	**$ Change**
Personnel	$ 2,257	$ 1,065	$ 1,192
Professional services	817	1,140	(323)
Facilities	315	289	26
Other	1,032	141	891
Total general and administrative expenses	$ 4,421	$ 2,635	$ 1,786

General and administrative expenses were $4.4 million for the three months ended March 31, 2022, compared to $2.6 million for the three months ended March 31, 2021. The increase of approximately $1.8 million was primarily due to:

- $1.2 million of increased personnel costs due to the requirements of operating as a public company, which included $0.5 million of increased stock-based compensation expense;
- $0.3 million of decreased professional service costs, primarily due to hiring to support the requirements of operating as a public company; and
- $0.9 million of increased other costs, primarily driven by $0.7 million of increased insurance costs associated with public company management liability insurance.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations through March 31, 2022 primarily through the issuance of convertible promissory notes for aggregate cash proceeds of $11.0 million, the issuance and sale of shares of our Series A and Series B preferred stock for aggregate cash proceeds of $116.3 million and the issuance and sale of shares of our common stock in our IPO in May 2021 for net proceeds of approximately $109.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Jazz Collaboration

In April 2022, we entered into the Collaboration Agreement with Jazz. Under the terms of the Collaboration Agreement, we received an upfront payment of $15.0 million in April 2022. We are eligible to receive up to $520.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products. In addition, we are eligible to receive tiered mid-single digit royalties based on Jazz's, and any of its affiliates' and sublicensees', annual net sales of Licensed Products, subject to reduction in specified circumstances.

Term Loan Facility

In April 2022, we entered into an amended and restated loan and security agreement, or the Loan Agreement, with Pacific Western Bank, or PWB, which amended and restated in its entirety our previous loan and security agreement with PWB. Under the terms of the Loan Agreement, PWB made available term loans in an aggregate principal amount of up to $40.0 million, of the Term Loans, consisting of (i) a term loan in the aggregate principal amount of up to $20.0 million available at any time until February 28, 2024, or as extended to August 31, 2024 upon the satisfaction of certain conditions set forth in the Loan Agreement (such date, the "Amortization Date"), and (ii) a term loan in the aggregate principal amount of up to $20.0 million available at any time until the Amortization Date upon the acceptance by the FDA of two IND submissions on or before March 31, 2023. As of May 10, 2022, the Term Loans remain undrawn.

The Term Loans bear interest on the outstanding daily balance at a floating annual rate equal to greater of: (i) 0.5% above the prime rate then in effect or (ii) 4.50%. If the prime rate changes throughout the term, the interest rate is adjusted effective on the date of the prime rate change. All interest chargeable under the Loan Agreement is computed on a 360-day year for the actual number of days elapsed, with interest payable monthly. The Loan Agreement provides for interest-only payments until the Amortization Date, at which time the aggregate outstanding principal balance of the Term Loans is required to be repaid in monthly installments on a 24-month repayment schedule. All unpaid principal and accrued and unpaid interest with respect to the Term Loans is due and payable in full on February 28, 2026, as extended to August 31, 2026 upon the satisfaction of certain conditions set forth in the Loan Agreement. At our option, we may elect to prepay all, or any part, of the outstanding Term Loans at any time without premium or penalty.

We are obligated to pay PWB a fee in the event of certain corporate transactions equal to either (i) the greater of (a) $200,000 and (b) 2.00% of the amount drawn under the Term Loans for a transaction occurring on or prior to March 31, 2023, or (ii) for any transaction occurring thereafter, the greater of (a) $400,000 and (b) 4.00% of the amount drawn under the Term Loans, which fee is referred to as a Success Fee. The Success Fee survives ten years from the date of payment of the Term Loans in full, such that, if the Loan Agreement is terminated prior to the payment of the Success Fee, we will remain obligated to pay the Success Fee upon the occurrence of a Success Fee Event during such ten-year period.

Under the Loan Agreement, we are required to comply with certain negative covenants, which among other things, restrict us from incurring future debt or granting liens, effectuating a merger or consolidation with or into any other business organization, paying dividends or making

certain other distributions, selling or otherwise transferring our assets, and making investments in any entities or instruments, subject, in each case, to certain exceptions specified in the Loan Agreement. The Loan Agreement also contains standard affirmative covenants, including with respect to the issuance of audited consolidated financial statements, insurance, and maintenance of good standing and government compliance in our state of formation. On or before September 30, 2023, we are required to raise aggregate gross cash process of at least $50.0 million from the sale or issuance of our equity or from strategic partnerships or any similar transaction. From after receipt of those proceeds, we are required to maintain at all times at least $20.0 million of unrestricted cash in accounts with PWB. Our failure to comply with any of the foregoing covenants would result in an event of default under the Loan Agreement.

Plan of Operation and Future Funding Requirements

We use our capital resources primarily to fund operating expenses, primarily research and development expenditures. We plan to increase our research and development expenses for the foreseeable future as we continue the preclinical development and move into clinical development of our product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current product candidates or any future product candidates, if at all. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. Further, inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation had a material effect on our financial statements included elsewhere in this Quarterly Report; however, our operations may be adversely affected by inflation in the future.

Due to our significant research and development expenditures, we have accumulated substantial net losses in each period since inception. We have incurred an accumulated deficit of $268.2 million through March 31, 2022. We expect to continue to incur substantial and increasing expenses and net losses for the foreseeable future, as we continue to advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company.

Based on our current research and development plans, we expect that our existing cash and cash equivalents of $143.7 million, along with the $15.0 million upfront payment received under our Collaboration Agreement and the first $20.0 million tranche under our Loan Agreement, will be sufficient to fund our operations through at least the fourth quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect.

The timing and amount of our operating expenditures will depend largely on:

- the scope, progress, timing, costs and results of researching and developing our current product candidates or any future product candidates, including with respect to our planned clinical trials of WTX-124 and WTX-330; the costs associated with attracting, hiring and retaining skilled personnel and consultants as our preclinical and clinical activities increase;
- the cost of manufacturing our product candidates WTX-124, WTX-330, and any future product candidates for clinical trials and, if we are able to obtain marketing approval, for commercial sale;
- the costs of any third-party products used in our planned combination clinical trials that are not covered by such third parties or other sources;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) as a result of the COVID-19 pandemic;
- the success of our collaboration with Jazz;
- the timing of, and the cost involved in, obtaining marketing approval for WTX-124 and WTX-330, or any future product candidates, and our ability to obtain marketing approval and generate revenue from any potential commercial sales of such product candidates;
- the cost of building a sales force in anticipation of product commercialization and the cost of commercialization activities for WTX-124, WTX-330, or any future product candidates if we receive marketing approval, including marketing, sales and distribution costs;
- the potential emergence of competing therapies and other adverse market developments;
- the amount and timing of any payments we may be required to make pursuant to our license agreement with Harpoon Therapeutics, Inc., or Harpoon, or other future license agreements or collaboration agreements;
- our ability to establish future collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any product liability or other lawsuits related to our product candidates;

- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Our existing cash and cash equivalents will not be sufficient to complete development of WTX-124, WTX-330 or any other product candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financing. We may also consider entering into collaboration arrangements or selectively partnering for clinical development and commercialization. The sale of additional equity may result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations or our ability to incur additional indebtedness or pay dividends, among other items. If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
(in thousands)	**2022**	**2021**
Net cash (used in) provided by:		
Operating activities	$ (13,951)	$ (7,326)
Investing activities	(28)	(13)
Financing activities	159	(538)
Net decrease in cash, cash equivalents and restricted cash	$ (13,820)	$ (7,877)

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2022 was $14.0 million, compared to $7.3 million for the three months ended March 31, 2021. This increase of approximately $6.6 million was primarily attributable to an increase in net loss of $7.9 million for the three months ended March 31, 2022 compared to the three months ended March 31, 2021.

Investing Activities

Net cash used in investing activities for each of the three months ended March 31, 2022 and 2021 was nearly zero.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2022 was $0.2 million, compared to $0.5 million used in financing activities for the three months ended March 31, 2021. This increase of $0.7 million was primarily attributable to costs incurred in connection with our IPO.

Contractual Obligations

Overview

In the normal course of business, we enter into agreements with CROs, contact manufacturers, vendors and other third parties for preclinical studies, manufacturing services and other services and products for operating purposes. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation.

Term Loan Facility

See "Liquidity and Capital Resources – Sources of Liquidity – Term Loan Facility" for a description of our Loan Agreement. As of May 10, 2022, the Term Loans remain undrawn.

Clinical Trial Collaboration and Supply Agreement

In August 2021, we entered into a Clinical Trial Collaboration and Supply Agreement, or Clinical Supply Agreement, with Merck & Co., Inc., or Merck, to evaluate WTX-124 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy. The planned clinical trial will be conducted by us and is designed to evaluate the safety and preliminary efficacy of WTX-124 as a monotherapy and in combination with pembrolizumab in patients with solid tumors. Under the terms of the Clinical Supply Agreement, we will sponsor the study

and Merck will supply us with pembrolizumab in exchange for jointly owning any inventions or discoveries relative to the combined use of WTX-124 and pembrolizumab. Each party is responsible for its own internal costs and expenses to support the trial.

Lease Agreements

In April 2019, we entered into an operating lease for approximately 9,949 square feet of office and laboratory space which commenced in April 2019 and terminates in March 2024. Total estimated base rent payments over the remaining term of the lease are approximately $1.8 million.

In March 2021, we entered into a short-term lease for approximately 7,500 square feet of office and laboratory space which commenced in April 2021 and terminates in May 2022. Total estimated base rent payments over the remaining term of the lease are approximately $0.1 million.

In June 2021, we entered into an operating lease for approximately 25,778 square feet of office and laboratory space in Watertown, Massachusetts, which will serve as our future headquarters. The lease term is targeted to commence in May 2022 and has an approximate eight-year term. Total estimated base rent payments over the term of the lease are approximately $19.3 million.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates which include, but are not limited to, leases, accrued expenses and stock-based compensation expense. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from those estimates under different assumptions or conditions.

There were no material changes to our critical accounting policies and estimates as reported in the Annual Report on Form 10-K.

JOBS Act Accounting Election and Smaller Reporting Company Implications

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of reduced disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act if we are a smaller reporting company with less than $100 million in annual revenue.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, or the Exchange Act, and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2022, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, or Quarterly Report, including our condensed consolidated financial statements and the related notes and Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and future growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

We are an early-stage biopharmaceutical company with a limited operating history upon which our business and prospects can be evaluated. We commenced operations in 2017. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, developing and optimizing our platform technology, identifying potential product candidates, enhancing our intellectual property portfolio, undertaking research and preclinical studies and enabling manufacturing for our development programs. Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any approved products of commercial value. In addition, we currently only have two product candidates that we are developing independently, WTX-124 and WTX-330, neither of which has entered clinical development, and all of our other development programs are in discovery or preclinical stages. We have not yet demonstrated an ability to successfully submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or the FDA, or successfully complete any Phase 1, Phase 2 or pivotal clinical trials, obtain regulatory approvals, manufacture a clinical- or commercial-scale product, or arrange for a third party to do so on our behalf, or conduct the sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception and have not yet generated any revenue. If our product candidates are not successfully developed and approved, we may never generate any revenue. Our net loss was $15.3 million for the three months ended March 31, 2022. As of March 31, 2022, we had an accumulated deficit of $268.2 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as WTX-124, WTX-330 and any future product candidates advance through preclinical studies and into clinical trials, and as we expand our clinical, regulatory, quality and manufacturing capabilities and incur additional costs associated with operating as a public company. If we obtain marketing approval for any of our product candidates, we will incur significant commercialization expenses for marketing, sales, manufacturing and distribution. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to develop commercial capabilities, and we may not be successful in doing so. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

To date, we have not generated any revenue from our product candidates or product sales, we do not expect to generate any revenue from the sale of products for a number of years and we may never generate revenue from the sale of products. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our ongoing and planned preclinical studies;
- successfully submit our INDs to the FDA for WTX-124, WTX-330 and any future product candidates;
- successfully initiate clinical trials for WTX-124, WTX-330 and any future product candidates;
- successfully enroll subjects in, and complete, our planned clinical trials and future clinical trials;
- initiate and successfully complete all safety and efficacy studies to obtain U.S. and foreign regulatory approval for our product candidates;
- establish clinical and commercial manufacturing capabilities or make arrangements with third party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively compete with other therapies;

- obtain and maintain healthcare coverage and adequate reimbursement;
- enforce and defend intellectual property rights and claims; and
- maintain a continued acceptable safety profile of our products following approval.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses we may incur in connection with these activities prior to generating product revenue. In addition, we may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will need to obtain substantial additional funding to finance our operations and complete the development and any commercialization of WTX-124, WTX-330 and any future product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate one or more of our research and development programs or other operations.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to incur increasing expenses and operating losses over the next several years as we pursue clinical development of our product candidates and implement the additional infrastructure necessary to support our operations as a public reporting company. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for WTX-124, WTX-330 or any other product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Some of these expenses may be incurred in advance of marketing approval and could be substantial.

As of March 31, 2022, we had cash and cash equivalents of $143.7 million. Our existing cash and cash equivalents will allow us to complete the development of WTX-124 through dose escalation and expansion trials as a monotherapy or in combination with an immune checkpoint inhibitor and the development of WTX-330 through dose escalation and expansion trials as a monotherapy or in combination with an immune checkpoint inhibitor.

Our cash and cash equivalents will not be sufficient to complete development of WTX-124, WTX-330 or any other product candidate. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed, on attractive terms or at all, would have a negative effect on our financial condition and our ability to develop and commercialize our current and any future product candidates, and otherwise pursue our business strategy and we may be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

In addition, our cash forecasts are based on assumptions that may prove to be wrong, and we could use our available capital resources earlier than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional financing sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of researching and developing our current product candidates or any future product candidates, including with respect to our planned clinical trials of WTX-124 and WTX-330;
- the costs associated with attracting, hiring and retaining skilled personnel and consultants as our preclinical and clinical activities increase;
- the cost of manufacturing our lead product candidates, WTX-124, WTX-330 and any future product candidates for clinical trials and, if we are able to obtain marketing approval, for commercial sale;
- the costs of any third-party products used in our planned combination clinical trials that are not covered by such third parties or other sources;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) as a result of the COVID-19 pandemic;
- the timing of, and the cost involved in, obtaining marketing approval for WTX-124, WTX-330 or any future product candidates, and our ability to obtain marketing approval and generate revenue from any potential commercial sales of such product candidates;
- the cost of building a sales force in anticipation of product commercialization and the cost of commercialization activities for WTX-124, WTX-330 or any future product candidates if we receive marketing approval, including marketing, sales and distribution costs;
- the potential emergence of competing therapies and other adverse market developments;
- the amount and timing of any payments we may be required to make pursuant to our license agreement with Harpoon Therapeutics, Inc., or Harpoon, or other future license agreements or collaboration agreements;

- our ability to establish future collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any product liability or other lawsuits related to our product candidates;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Except for the first $20.0 million tranche under our amended and restated loan and security agreement, or the Loan Agreement, with Pacific Western Bank, or PWB, we do not have any committed external source of funds and adequate additional financing may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions resulting from the ongoing COVID-19 pandemic and any disruptions to, or volatility in, the credit and financial markets in the United States and worldwide that arise from the pandemic. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts or other operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our platform technology or product candidates.

Unless and until we can generate a substantial amount of product revenue, we expect to seek additional capital through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our financing plans or the terms of such financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. The incurrence of indebtedness would result in payment obligations and could require us to comply with certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to declare dividends, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Further, our ability to obtain additional debt financing may be limited by covenants we have made under our Loan Agreement, including our pledge to PWB of substantially all of our assets, other than our intellectual property, as collateral. If we raise additional funds through collaborations and licensing arrangements with third parties, we may have to relinquish valuable rights to our platform technology or product candidates or grant licenses on terms unfavorable to us. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

We have a term loan facility that requires us to comply with certain operating covenants and places restrictions on our operating and financial flexibility.

All outstanding obligations under the Loan Agreement are secured by our Company's personal property (exclusive of any intellectual property), and are subject to acceleration upon an event of default. Under the Loan Agreement, we are required to comply with certain negative covenants, which among other things, restrict us from incurring future debt or granting liens, effectuating a merger or consolidation with or into any other business organization, paying dividends or making certain other distributions, selling or otherwise transferring our assets, and making investments in any entities or instruments, subject, in each case, to certain exceptions specified in the Loan Agreement. The Loan Agreement also contains standard affirmative covenants, including with respect to the issuance of audited consolidated financial statements, insurance, and maintenance of good standing and government compliance in our state of formation. On or before September 30, 2023, we are required to raise aggregate gross cash process of at least $50.0 million from the sale or issuance of our equity or from strategic partnerships or any similar transaction. From after receipt of those proceeds, we are required to maintain at all times at least $20.0 million of unrestricted cash in accounts with PWB. Our failure to comply with any of the foregoing covenants would result in an event of default under the Loan Agreement.

Our financial obligations and contractual commitments under the Loan Agreement could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

Under our Loan Agreement, the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, assets or condition is an event of default. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness, which

includes substantially all of our assets other than our intellectual property. In addition, the covenants under our Loan Agreement, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing.

Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition.

Changes in tax laws or in their implementation or interpretation may adversely affect our business or financial condition. The Tax Cuts and Jobs Act of 2019, or TCJA, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, significantly revises the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely and, as a result of amendments made by the CARES Act, such net operating losses arising in taxable years beginning before January 1, 2021 are generally eligible to be carried back up to five years), one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

In addition to the CARES Act, as part of Congress's response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. Regulatory guidance under the TCJA and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. Also, as a result of the changes in the U.S. presidential administration and control of the U.S. Senate in 2021, additional tax legislation may be enacted; any such additional legislation could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the TCJA and additional tax legislation.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. As of December 31, 2021, we had federal and state net operating loss carryforwards of $80.3 million and $74.5 million, respectively. Under Section 382 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain stockholders over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our prior private placement financings or other transactions, we may have in the past experienced, and we may in the future experience as a result of subsequent changes in our stock ownership, some of which are outside our control, an ownership change for purposes of Section 382. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could result in increased future tax liability to us and could have an adverse effect on our future results of operations. There is also a risk that due to regulatory changes, such as suspension of the use of net operating losses, or for other unforeseen reasons, our existing net operating losses could expire or otherwise become unavailable to offset future income tax liabilities. As described above in "Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition," the TCJA, as amended by the CARES Act, includes changes to U.S. federal tax rates and rules governing net operating loss carryforwards that may significantly impact our ability to utilize net operating losses to offset taxable income in the future. In addition, state net operating losses generated in one state cannot be used to offset income generated in another state. For these reasons, we may be unable to use a material portion of our net operating losses and other tax attributes.

Risks Related to the Discovery, Development, Regulatory Approval and Commercialization of Our Product Candidates

We are early in our development efforts and our current product candidates will require successful completion of preclinical and clinical development before we can seek regulatory approval for any product candidates.

We are early in our development efforts and have invested substantially all of our efforts and financial resources in building our PREDATOR platform and developing our initial INDUKINE molecules by leveraging our PREDATOR platform. We have yet to advance any of our lead product candidates into clinical trials. Additionally, we have a portfolio of programs that are in even earlier stages of preclinical development and may never advance to clinical-stage development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Our business is highly dependent on the success of our initial INDUKINE molecules, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and launch a product commercially.

Our business and future success is highly dependent on our ability to obtain regulatory approval of and then successfully launch and commercialize our initial INDUKINE molecules, including our most advanced product candidates, WTX-124 and WTX-330, each of which is in preclinical development.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our first clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we

have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union.

To date, we have only had limited interactions with the FDA regarding our clinical development plans. We may experience issues surrounding preliminary trial execution, such as delays in FDA acceptance of our INDs, revisions in trial design and finalization of trial protocols, difficulties with patient recruitment and enrollment, quality and provision of clinical supplies, or early safety signals.

We are not permitted to market any biological product in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

FDA approval of a BLA is not guaranteed, and the review and approval process is expensive and uncertain and may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidate that we develop based on the completed clinical trials.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on our ability to successfully develop and commercialize of WTX-124, WTX-330 and any future product candidates. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies and clinical trials with favorable results;
- acceptance of INDs by the FDA or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- receipt of marketing approvals from applicable regulatory authorities, including BLAs from the FDA and maintaining such approvals;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of scientists and business people who can develop our products and technology.

Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for WTX-124, WTX-330 or any future product candidates.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of WTX-124, WTX-330 and any future product candidates, which may never occur. However, given our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our current or any future product candidates, we may not be able to generate sufficient revenue to continue our business.

Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any products of commercial value.

The success of our business depends primarily upon our ability to discover, develop and commercialize products based on our novel PREDATOR platform. While we have had favorable preclinical study results related to WTX-124 and WTX-330, both of which we are developing by leveraging our PREDATOR platform, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. We have no assurance that our PREDATOR platform will be able to produce product candidates that will successfully progress from preclinical studies into clinical development and ultimately marketing approval. We have invested substantially all of our efforts and financial resources in building our PREDATOR platform and developing our initial INDUKINE molecules by leveraging our PREDATOR platform, and our future success is highly dependent on the continued successful development of our platform and product candidates that we develop by leveraging our platform. Because all of our product candidates are based upon our PREDATOR platform, any development problems we may experience in the future related to any of our product candidates has the potential to impact the development of our other product candidates and any such development problems have the potential to cause significant delays or unanticipated costs and may ultimately not be able to be solved.

In addition, the clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate may vary according to the type, complexity, novelty and intended use and market of the potential

products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. As a result, we may face a greater regulatory burden to initiate clinical trials or to obtain regulatory approval of our product candidates as compared to product candidates based on more established technology. In addition, any product candidates for which we may be able to obtain marketing approval may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

Manufacturing INDUKINE molecules is subject to risk since they are a novel class of multi-domain biologics that include protease cleavable linkers, and they have never been produced on a clinical or commercial scale. We may be unable to manufacture INDUKINE molecules at the scale needed for clinical development and commercial production on a timely basis or at all, which would adversely affect our ability to conduct clinical trials and seek regulatory approvals or commercialize our programs, which would have an adverse effect on our business.

The manufacturing cell line currently in use to develop INDUKINE manufacturing processes has not been used to manufacture multi-domain proteins that include our protease cleavable linkers. The presence of these linkers presents a risk that unintended proteolysis may occur during the manufacture of INDUKINE molecules and that undesired fragments may not be able to be sufficiently removed by the purification process. The novel multi-domain composition of INDUKINE molecules may present a risk due to its complexity and challenges inherent to the manufacture of biologics. As a result, the risk of delays or failure in the manufacture of our INDUKINE molecules is high. Before we can commence clinical trials for a product candidate, the manufactured INDUKINE molecules must complete extensive analytical testing and be qualified for use in human studies. We cannot be certain of the timely completion or outcome of our analytical testing and suitability for human studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical material or if the outcome of our analytical testing will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our product candidates or any future preclinical programs on the timelines we expect, if at all, and we cannot be sure that the submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. In addition, we cannot be certain that we will be able to produce product candidates at the scale required for our clinical trials and, for any approved products, commercial production on a timely basis or at all, which could also have an adverse effect on our business.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have chosen to initially develop our lead product candidate, WTX-124, for the treatment of advanced solid tumors. We plan to develop our second product candidate, WTX-330, for the treatment of relapsed or refractory advanced or metastatic tumors or lymphoma. Nevertheless, our development efforts will be limited to a small number of cancer types and we may forego or delay pursuit of opportunities in other cancer types that may prove to have greater potential. Likewise, we may forego or delay the pursuit of opportunities with other potential product candidates that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

None of our product candidates has advanced into a clinical trial, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to successfully submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Preclinical studies and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our current and any future product candidates is high. It is impossible to predict when or if any of our product candidates will successfully complete preclinical studies or clinical trials evaluating their safety and effectiveness in humans or will ultimately receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. To date, we have never advanced a product candidate into a clinical trial. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, while we have conducted certain preclinical studies of WTX-124 and WTX-330, we do not know whether either of these product candidates will perform in our planned clinical trials as it has performed in these prior preclinical studies. Additionally, if we successfully commence clinical trials there can be no assurance that success in early clinical trials will lead to success in later clinical trials. Many companies in the biopharmaceutical and biotechnology industries have suffered

significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to obtain regulatory authorizations to commence a clinical trial;
- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from a trial protocol or drop out of a trial or fail to conduct the trial in accordance with regulatory requirements;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate or subjects may fail to enroll or remain in clinical trials at the rate we expect;
- subjects that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subject from the trial, increase the needed enrollment size for the clinical trial or extend its duration;
- subjects may choose an alternative treatment for the indication for which we are developing our product candidates, or participate in competing clinical trials;
- subjects may experience severe or unexpected drug-related adverse effects;
- clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results;
- we may decide to, or regulators or IRBs or ethics committees may require us to, make changes to a clinical trial protocol or conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;
- we may need to add new or additional clinical trial sites;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may experience manufacturing delays, and any changes to manufacturing processes or third party contractors that may be necessary or desired could result in other delays;
- we or our third party contractors may experience delays due to complications associated with the continuing COVID-19 pandemic;
- the cost of preclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate or greater than our available financial resources;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or we may not be able to obtain sufficient quantities of combination therapies for use in clinical trials;
- reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and

- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond the clinical trials and testing that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these clinical trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with any of product candidates, we may:

- incur additional unplanned costs;
- be required to suspend or terminate ongoing clinical trials;
- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing or other requirements;
- be required to perform additional clinical trials to support approval;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- have the product removed from the market after obtaining marketing approval;
- be subject to lawsuits; or
- experience damage to our reputation.

Conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition to the factors above, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions, which may be costly, time consuming and may not be successful at all.

Our failure to successfully initiate and complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business. We cannot provide assurances that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our clinical trials. Significant preclinical study or clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- the patient eligibility and the inclusion and exclusion criteria defined in the protocol;
- the size and health of the patient population required for analysis of the trial’s primary endpoints;
- the proximity of patients to trial sites;

- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- our ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control, including the impacts of the COVID-19 pandemic, that may limit the availability of patients, principal investigators or staff or clinical sites.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

Our product candidates may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable or unexpectedly severe side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. We have not yet initiated clinical trials for any of our product candidates and it is likely that, as is the case with many treatments for cancer, there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, by design, clinical trials rely on a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients is exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- regulatory authorities may withdraw or limit their approval of such product candidates;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- we may suffer reputational harm.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

The COVID-19 pandemic or any future surges, including as a result of new variants and subvariants of the virus, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises such as the COVID-19 pandemic or similar outbreaks could adversely impact our business. In response to the COVID-19 pandemic, governments throughout the world have implemented a variety of quarantines, travel restrictions and other public health and safety measures that have impacted, and may continue to impact, our operations. The ultimate extent to which COVID-19 or any future surges, including as a result of new variants and subvariants of the virus, impacts our operations, including our preclinical testing, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and the actions taken to contain COVID-19 or treat its impact, among others. Any negative impact COVID-19 has on the execution of our product development plans could adversely affect our ability to timely submit INDs for product candidates, negatively affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Effects of the COVID-19 pandemic that may delay or otherwise adversely affect our ongoing and planned preclinical activities, our planned clinical trials as well as our business generally, include:

- delays related to COVID-19 disruptions at CROs and contract manufacturers, or in the supply chain;
- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff who, as healthcare providers, may have heightened exposure to COVID-19;
- delays or difficulties in enrolling and retaining patients in clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials;
- difficulties interpreting data from clinical trials due to the possible effects of COVID-19 on patients;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; and
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of many of our employees working remotely, including those hired during the COVID-19 pandemic.

Any of these effects, and other effects of the COVID-19 pandemic, including future outbreaks, the emergence of new variants and subvariants of the virus, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates.

Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We expect to develop WTX-124 and WTX-330, and potentially future product candidates, in combination with third-party drugs, some of which may still be in development, and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such drugs.

We intend to develop WTX-124 and WTX-330, and likely other future product candidates, in combination with third-party cancer drugs, which may be either approved or unapproved. For example, we plan to conduct clinical trials of WTX-124 and WTX-330 both as monotherapy and in combination with immune checkpoint inhibitors. Our ability to develop and ultimately commercialize our current product candidates, and any future product candidates, used in combination with third-party drugs will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all. Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing such third-party drugs in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, operating results, or prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, our planned clinical trials for WTX-124 and WTX-330 in combination with an immune checkpoint inhibitor may result in adverse events based on the combination therapy that may negatively impact the reported safety profile of the monotherapy in such clinical trials. Checkpoint inhibitors have been shown to have adverse events, including immune-related adverse events involving the lung, liver and other organ systems, which may limit the maximum dose in our clinical trials or otherwise negatively impact our combination clinical trials. In addition, the FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the third-party drug and not our product candidate. Developments related to the third-party drug may also impact our clinical trials for the combination as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the third-party drug's safety or efficacy profile, changes to the availability of the third-party drug, quality, and manufacturing and supply issues with respect to the third-party drug.

If we are able to obtain marketing approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the third-party drug, this may require us to work with such third party to satisfy such a requirement. We would also continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the third-party drug used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such drug. Similarly, if the third-party drugs we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We may not be successful in our efforts to identify or discover additional product candidates.

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify or discover viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our current product candidates or to develop suitable additional product candidates through internal research programs, which could materially adversely affect our future growth and prospects.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or following commercial sale, and any product liability insurance we may obtain may not cover all damages from such claims.

We are exposed to potential product liability risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. The use of product candidates by us in clinical trials, and any sale of approved products in the future, may expose us to liability claims. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval thereof, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the development or commercialization of our product candidates or any products for which we may have received marketing approval. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;

- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact; and
- the inability to commercialize any of our product candidates, if approved.

Although we will seek to procure and maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be materially harmed.

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any products that receive regulatory approval, either on our own or together with collaborators.

We have never commercialized a product candidate. We currently have no sales force or marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to one or more third parties.

Factors that may affect our ability to commercialize our product candidates on our own include our ability to recruit and retain adequate numbers of effective sales and marketing personnel and obtain access to or persuade adequate numbers of physicians to prescribe our product candidates, as well as any unforeseen costs we may incur in connection with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. To the extent we need to rely upon one or more third parties, we may have little or no control over the marketing and sales efforts of those third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We will also face competition in any search for third parties to assist us with sales and marketing efforts for our product candidates. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of pharmaceutical and biotechnology companies of various sizes. Some of these competitive therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our initial product candidates for the treatment of cancer and have not commenced clinical trials of or received marketing approval for any of our product candidates. There are already a variety of available therapies marketed for cancer and some of the currently approved therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved therapies are well-established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates. Competition may further increase with advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

We are aware of a number of companies that are developing cytokines as immunotherapies, as well as different modalities, including monoclonal antibodies, cell therapies, oncolytic viruses and vaccines.

Our lead product candidate, WTX-124, if approved, may face competition from other Interleukin-2, or IL-2, based cancer therapies. Proleukin (aldesleukin), a synthetic protein very similar to IL-2, is approved and marketed for the treatment of metastatic renal cell carcinoma and melanoma. In addition, we are aware that a number of other companies have modified IL-2 programs in development for the treatment of cancer, including Alkermes Plc, Ascendis Pharma A/S, Asher Biotherapeutics, Inc., BioNTech SE, Medicenna Therapeutics Corp., Neoleukin Therapeutics, Inc., F. Hoffmann-La Roche AG, or Roche, Synthekine, Inc., Synthorx, Inc. (Sanofi) and Xilio Therapeutics, Inc.

There are no approved IL-12 therapies currently on the market for the treatment of cancer. However, if approved, WTX-330 may face competition from other IL-12 cytokine programs in clinical and preclinical development for oncology indications, including programs from Sanofi S.A. (Amunix), DragonFly Therapeutics, Inc., Juno Therapeutics, Inc. (Bristol-Myers Squibb Company), Oncorus, Inc., Turnstone Biologics Corp. (partnered with Takeda Pharmaceutical Company Limited, or Takeda), Philogen S.p.A., Codiak BioSciences, Inc., Oncosec Medical Incorporated, and Xilio Therapeutics, Inc.

If approved, WTX-613 may face competition from other Interferon alpha, or IFNα, cancer therapies. Intron-A, a recombinant IFNα-2b molecule marketed by Merck & Co., Inc., has been approved by the FDA for the treatment of several forms of cancer, including specific types of leukemia and lymphoma. We are aware of other IFNα programs targeting the treatment of cancer in development by Immunomedics (acquired by Gilead Sciences, Inc.) and Takeda. Roferon A, a recombinant IFNα-2a molecule developed and marketed by Roche for the treatment of specific types of leukemia, was discontinued globally in 2020.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. We also compete with these organizations in establishing clinical trial sites and patient registration for clinical trials, as well as in recruiting and retaining qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel product candidates or to in-license novel product candidates that could make our product candidates less competitive or obsolete. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. The availability of competing products could limit the demand and the price we are able to charge for product candidates we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

The sizes of the potential markets for our product candidates are difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and, if our product candidates are approved, will ultimately depend on, among other things, the indications for which our product candidates are approved for sale, any drugs with which our product candidates are co-administered, the success of competing therapies and therapeutic approaches, acceptance by the medical community, patient access, product pricing and reimbursement. Our estimates of the potential market opportunities for our product candidates are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

The successful commercialization of our product candidates will depend in part on the extent to which we obtain and maintain favorable coverage, adequate reimbursement levels and pricing policies with third party payors.

The availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, managed care organizations, and private health insurers, are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates, if approved, or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates, if approved. Even if our product candidates are approved and we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the United States, third-party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid

programs increasingly are used as models in the United States for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success.

If any product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors, and others in the medical community. For example, cancer treatments like chemotherapy, radiation therapy and certain existing immunotherapies are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product, if approved for commercial sale, will depend on a number of factors, including:

- its efficacy, safety and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the product's convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product is approved;
- the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments;
- the recommendations with respect to the product in guidelines published by scientific organizations;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement, including, if applicable, with respect to the use of the product as a combination therapy;
- the strength of marketing, sales and distribution support;
- the effectiveness of our sales and marketing efforts;
- the approval of other new products for the same indications; and
- our ability to offer the product for sale at competitive prices.

If we obtain marketing approval for a product but such product does not achieve an adequate level of market acceptance, we may not generate or derive significant revenue from that product and our business, financial condition and results of operations may be adversely affected.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of non-patent exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any product candidates.

We depend, and expect to continue to depend, upon third parties, including independent investigators and CROs, to conduct preclinical studies and our planned clinical trials. We expect to have to negotiate budgets and contracts with CROs and trial sites, and any of these third parties may terminate their engagements with us at any time, any of which may result in delays to our development timelines and increased costs.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current Good Clinical Practices, or cGCP, requirements for clinical trials, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP requirements. In addition, our clinical trials must be conducted with biologic product produced under current Good Manufacturing Practice, or cGMP, requirements.

Our failure or any failure by these third parties to comply with the applicable regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which could materially impact our ability to meet our desired clinical development timelines. Though we plan to carefully manage our relationships with CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

The manufacturing of biologics is complex and we do not have our own clinical manufacturing capabilities. We will rely on third parties to produce preclinical, clinical and commercial supplies of all current and any future product candidates.

To date, we have produced limited quantities of our product candidates at our own facilities for preclinical evaluation. However, going forward we will rely on third-party contract manufacturers to manufacture some of our preclinical supply and all of our clinical trial supply. We do not own manufacturing facilities capable producing drug products at clinical scale. We have in the past experienced delays in receiving preclinical product supplies from third-party manufacturers and there can be no assurance that our preclinical and clinical development product supplies from third parties will not in the future be limited or interrupted, or be of satisfactory quality or continue to be available at acceptable prices. Additionally, the process of manufacturing biologics is complex, highly regulated, and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our contract manufacturing organizations, or CMOs, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business.

We have engaged CMOs to provide certain services to support our clinical and preclinical development. Pursuant to the terms of separate contract manufacturing services agreements, we have engaged one CMO to provide drug substance manufacturing process development and to manufacture WTX-124 and WTX-330 drug substance to cGMP specifications for use in the further manufacture of clinical supply, a second CMO to provide drug product manufacturing process development and to manufacture clinical supply of WTX-124 and WTX-330 vialled drug product to cGMP specifications, and a third CMO to provide drug substance manufacturing for WTX-613. To support the manufacture of clinical vialled drug product, our CMO will conduct substantial analytical testing of WTX-124 and WTX-330 vialled drug product. If our CMOs are unable to supply us with sufficient clinical grade quantities of WTX-124 or WTX-330, and we are unable to timely establish an alternate supply from one or more third-party contract manufacturers, we will experience delays in our development efforts as we seek to locate and qualify new manufacturers. In particular, any replacement of our CMOs could require significant effort and expertise

because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements. Additionally, contract manufacturers may rely on single source suppliers for certain of the raw materials for our preclinical and clinical product supplies. If current or future suppliers are delayed or unable to supply sufficient raw materials to manufacture product for our preclinical studies and clinical trials, we may experience delays in our development efforts as materials are obtained or we locate and qualify new raw material manufacturers. Further, for our planned combination clinical trials of WTX-124 or WTX-330 with immune checkpoint inhibitors, we will need to procure supply of the immune checkpoint inhibitors for use in the clinical trials. If we are unable to procure sufficient supply from third-party manufacturers or other sources, we may be required to purchase our supply of checkpoint inhibitors on the open market, which may result in significant additional expense.

The manufacturing process for a clinical candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with their standards, such as cGMPs. In the event that any of our CMOs fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. The transfer of the manufacturing of biologic products to a new CMO and any additional process development that may be necessary can be lengthy and involve significant additional costs. If we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new CMO would negatively affect our ability to develop product candidates in a timely manner or within budget.

Further, our reliance on third-party manufacturers exposes us to risks beyond our control, including the:

- inability to meet our drug specifications and quality requirements consistently;
- inability to initiate or continue preclinical studies or clinical trials of product candidates under development;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and drug quality issues, including related to scale-up of manufacturing;
- failure to comply with cGMP and similar foreign standards;
- reliance on a limited number of sources, and in some cases, single sources for drug components and raw materials, such that if we are unable to secure a sufficient supply of these drug components and raw materials, we will be unable to manufacture and sell our future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components and raw materials that are purchased from a sole or single source supplier;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruption of operations by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of an FDA Form 483 notice or warning letter, or as a result of the effects of the COVID-19 pandemic on third-party manufacturers;
- carrier disruptions or increased costs that are beyond our control;
- failure to deliver our drugs under specified storage conditions and in a timely manner; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production, any of which could result in a failure to begin our clinical trials or having to stop ongoing clinical trials. In addition, our CMOs and suppliers are subject to FDA inspection from time to time. Failure by our CMOs and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, our CMOs and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

In addition, our CMOs are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or CMO's facility, which could impact the contract supplier's or CMO's ability to manufacture drug product for us.

We have entered into, and may in the future seek to enter into, collaborations or other similar arrangements for our product candidates. If we are unable to enter into such collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into collaborations in the future on an asset-by-asset basis to maximize the value of each of our programs. For example, in April 2022, we entered into a Collaboration and License Agreement, or the Collaboration Agreement, with Jazz Pharmaceuticals Ireland Limited, or Jazz, pursuant to which we granted Jazz certain licenses to develop and commercialize products containing our Interferon alpha ("IFNα") INDUKINE™ molecule, WTX-613, as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria. We may also enter into collaborations in connection with our platform technology in order to advance the development of programs beyond our initial focus in cytokines. Such collaborations may include the development and commercialization of any of our product candidates or the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for our programs and platform technology. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view such product candidates as having the requisite potential to demonstrate safety and efficacy. We may also be restricted under future license agreements from entering into agreements on certain terms or at all with potential collaborators.

Existing and future collaborations involving our product candidates may pose significant risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed product candidates;
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated; and

- collaborations may be terminated, including for the convenience of the collaborator, and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Any collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. In addition, all of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report will apply to the activities of any of our collaborators.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for our PREDATOR platform and other proprietary technologies we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates and technology similar or identical to our product candidates and technology, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our PREDATOR platform, our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our PREDATOR platform and our product candidates that are important to our business; we also license and may in the future license or purchase additional patents and patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our PREDATOR platform, our product candidates and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

If the scope of the patent protection we or our potential licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot provide assurances that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. No consistent policy governing the scope of claims allowable in the field of engineered therapeutic proteins has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose our confidential or proprietary information before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications.

The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Pending patent applications cannot be enforced against third parties unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or any patent applications that we may license in the future will result in patents being issued. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even if patent applications we currently own or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from

competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether our PREDATOR platform or any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing new products that are similar to our product candidates, biosimilars of our product candidates, or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the U.S. Patent and Trademark Office, or USPTO, or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We rely on the Harpoon Agreement for patent rights with respect to our product candidates and may in the future acquire additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses.

We rely on our Second Amended and Restated Assignment and License Agreement, or the Harpoon Agreement, with Harpoon, pursuant to which we have non-exclusive and exclusive rights to technology that is incorporated into our PREDATOR platform, development programs and product candidates. The Harpoon Agreement gives us non-exclusive, sublicensable, worldwide rights to develop, manufacture, and commercialize products containing certain of Harpoon's patented technology and exclusive, irrevocable rights to certain other Harpoon inventions that may be made during a limited collaboration period. The Harpoon Agreement imposes disclosure, royalty payment and other obligations on us.

Moreover, the growth of our business may depend in part on our ability to acquire, in-license or use additional third-party intellectual property rights. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Licenses to additional third-party intellectual property, technology and materials that may be required for the development and commercialization of our product candidates or technology may not be available at all or on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our product candidates or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize our future product candidates or technologies, which could materially harm our business, financial condition, results of operations and growth prospects.

Under the Harpoon Agreement, Harpoon is responsible for prosecution and maintenance of the licensed patents and any future third party from whom we may license patent rights may similarly be responsible for prosecution and maintenance of such patents. We have limited control over the activities that are the responsibility of Harpoon, and would have limited control over the activities that are the responsibility of any future licensor, and it is possible that prosecution and maintenance of licensed patents by Harpoon or any future licensor may be less vigorous than had we conducted such activities ourselves. Furthermore, the Harpoon Agreement is subject to, and we expect our future license agreements may also be subject to, a reservation of rights by one or more third parties, including the licensor. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Disputes may arise regarding intellectual property subject to the Harpoon Agreement or any future license agreements of ours, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensor's ability to defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate any intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under the license agreement;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and any partners of ours; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks described in this Quarterly Report with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Harpoon and any potential future licensors might conclude that we have materially breached our license agreements and might therefore terminate the relevant license agreements, thereby removing our ability to develop and commercialize products and technology covered by such license agreements. If any of our current or future inbound license agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products that are covered by such license agreements and underlying patents, which might be identical to our products or product candidates. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects. Our business also would suffer if any current or future licensors fail to abide by the terms of the license or fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Any licensor of ours may have relied on third-party consultants or collaborators or on funds from third parties, such as the United States government, such that such licensor is not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies and product candidates are not adequate, we may not be able to compete effectively in our market.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive defense of intellectual property. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Our or our licensor's failure to comply with all such provisions during the patent process could result in abandonment or lapse of a patent or patent application that we own or license, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market and compete with us earlier than would otherwise have been the case.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies and our product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements and product candidates, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We seek or plan to seek patent protection for our PREDATOR platform and product candidates by filing and prosecuting patent applications in the United States and other countries as appropriate. However, we cannot predict:

- if and when patents will issue;
- if patents will issue with claims that cover our product candidates;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;

- whether any of our intellectual property will provide any competitive advantage;
- whether any of our patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate or defend litigation or administrative proceedings which may be costly regardless of whether we win or lose.

Additionally, we cannot be certain that the claims in our pending patent applications covering our product candidates, PREDATOR platform and research programs will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or technology or uses thereof in the United States or in other foreign countries. Even if patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates or technology is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. Various post-grant review proceedings, such as *inter partes* review, post-grant review and derivation proceedings, are available and may be pursued by any interested third party in the USPTO to challenge the patentability of claims issued in patents to us or our licensors. No assurance can be given as to the outcome of any such post-grant review proceedings. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a USPTO-administered post-grant review system that has affected patent litigation. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use polypeptides or nucleic acids that are similar to our product candidates or components of our product candidates but that are not covered by the claims of our patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;

- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates or technology;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future, and such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or technology we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

Our proprietary position in part depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of making or method of use. Although we have two issued patents with certain composition of matter claims with respect to WTX-124 and IL-12 INDUKINE molecules, we also have pending patent applications with other composition of matter claims with respect to our product candidates. We cannot be certain, however, that the claims in our pending patent applications, including those claims covering the composition of matter of our product candidates, will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our patents that have issued or may issue will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product candidates, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture. Method of use patents protect a specified method of using a product, such as a method of use for treating a particular medical indication. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent by enforcing patent rights or otherwise. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license and other agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our product candidates and PREDATOR platform, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms and related processes are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual

means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. However, we cannot provide assurance that these agreements and policies will not be breached by our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and that our trade secrets and other proprietary and confidential information will not be disclosed to publicly or to competitors.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post-grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe third party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If WTX-124, WTX-330, WTX-613 or another product candidate is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. For example, we have received, and we may in the future receive, correspondence from third parties or their legal counsel disclosing that such third party owns patents that may encompass one or more of our product candidates. It is also possible that a third party may file a lawsuit against us alleging infringement of its patents. The outcome of any such proceeding is uncertain and would likely result in the expenditure of significant financial resources and the diversion of management's time and resources, which could harm our business. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final

product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available on commercially reasonable terms or at all. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have certain intellectual property rights, under patents and patent applications that we own or will own and under the Harpoon Agreement, related to WTX-124, WTX-330, WTX-613 and other product candidates we may develop in the future. Our development of additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights directed to certain INDUKINE constructs we may not be able to obtain intellectual property to broad INDUKINE polypeptides or engineered INDUKINE constructs.

Our product candidates may also require specific formulations to work effectively and efficiently, and rights to such formulation technology may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific components, such as linkers and antibody fragments, that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we may collaborate with or sponsor research at academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration or sponsorship. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file lawsuits with infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay

substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Some of our patent applications have been granted or may be granted or allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that can cause the allowance of a patent application to be withdrawn. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will re-allow the application in view of the new material. Further, periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. We rely on our outside counsel and other professionals or our licensing partners to pay these fees due to the USPTO and non-U.S. government patent agencies and to help us comply with other procedural, documentary and other similar requirements and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates or technology could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that the patent covering our product candidate or technology, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates or technology. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on

this decision, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have obtained granted patents in the United States that we consider to be important for certain of our product candidates, however, we may have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue generic coverage of our PREDATOR platform or of our INDUKINE molecules outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other confidential information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within

applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of an NDA or BLA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product

candidate's safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations.

In order to market and sell our products in the European Union and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-U.S. approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the withdrawal of the United Kingdom from the EU, commonly referred to as Brexit. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to EU rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the body of EU law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the EU. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

We may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the European Medicines Agency, or EMA, will be precluded from approving another marketing application for the same product for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

We may seek orphan drug designations for our product candidates and may be unable to obtain such designations. Even if we do secure such designations and orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because

different products can be approved for the same condition. Further, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, to be more effective or to make a major contribution to patient care. Finally, orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the Court of Appeals concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Any product candidate for which we obtain marketing approval is subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved.

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. In September 2021, the FDA published final regulations which describe the types of evidence that the FDA will consider in determining the intended use of a drug or biologic. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

Failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Similar restrictions apply to the approval of products in the EU. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the EU's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion

of authorized drugs, which are strictly regulated in the EU and are also subject to EU Member State laws. The failure to comply with these and other EU requirements can also lead to significant penalties and sanctions.

We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek PRIME Designation in the EU for one or more of our product candidates but we might not receive such designations and, even if we do, such designations may not lead to a faster development or regulatory review or approval process.

In the EU, we may seek PRIME designation for our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims.

The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

We and our contract manufacturers are subject to significant regulation. The manufacturing facilities on which we rely may not continue to meet regulatory requirements, which could materially harm our business.

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing.

We or our contract manufacturer must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's current Good Laboratory Practice and cGMP regulations enforced through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidate. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. Any such consequence would severely harm our business, financial condition and results of operations.

We are conducting, and intend in the future to conduct, clinical trials for certain of our product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.

We are conducting, and intend in the future to conduct, one or more of our clinical trials with trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practice. The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the United States. In addition, while these clinical trials are subject to the applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant adverse impact on us or the trial results. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange rate fluctuations; and
- diminished protection of intellectual property in some countries.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, including from the COVID-19 pandemic, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

Accordingly, if a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other

disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our candidate products that do receive marketing approval.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the TCJA in 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, in December 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. In June 2021, the U.S. Supreme Court dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the CARES Act. These Medicare sequester reductions have been suspended through the end of March 2022. From April 2022 through June 2022 a 1% sequester cut will be in effect, with the full 2% cut resuming thereafter. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. This Executive Order also directs the U.S. Department of Health and Human Services, or HHS, to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic.

Current and future legislative efforts may limit the costs for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates

a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs the Department of Health and Human Services, or HHS, to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Finally, outside the United States, in some nations, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute any products for which we obtain marketing approval. Potentially applicable U.S. federal and state healthcare laws and regulations include the following:

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

False Claims Laws. The federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program.

HIPAA and HITECH. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

False Statements Statute. The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to HHS information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and ownership and investment interests by physicians and their immediate family members. As of January 1, 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

Analogous State and Foreign Laws. Analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third

party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Compliance with state, national and international privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to a variety of harms, including significant fines and penalties, litigation and reputational damage, any of which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate or are likely to operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including strict rules on the transfer of personal data to countries outside the European Union, including the United States.

Brexit has complicated data protection regulation in the United Kingdom because, as of January 1, 2021, the GDPR has been converted into United Kingdom law and the United Kingdom is now a "third country" under the GDPR, subject to a transition period. Unless the European Commission makes an 'adequacy finding' in respect of the United Kingdom before the expiration of the transition period, the United Kingdom will become an 'inadequate third country' under the GDPR and transfers of data from the EEA to the United Kingdom will require a 'transfer mechanism,' such as the standard contractual clauses. Furthermore, following the expiration of the specified period, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and EEA.

As a result, there is increased scrutiny on the extent to which clinical trial sites located in the EEA should apply the GDPR to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Actions are either in place or under way in the United States to enact similar legislation. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020, is creating similar risks and obligations as those created by GDPR, though the Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Additionally, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA.

In addition to the foregoing, any breach of privacy laws or data security laws, particularly resulting in a significant security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, could have a material adverse effect on our business, reputation and financial condition. As a data controller, we will be accountable for any third-party service providers we engage to process personal data on our behalf, including our CROs. There is no assurance that privacy and security-related safeguards we implement will protect us from all risks associated with the third-party processing, storage and transmission of such information.

New legislation proposed or enacted in Colorado, Illinois, Massachusetts, Nevada, New Jersey, New York, Rhode Island, Virginia, Washington and other states, and a proposed right to privacy amendment to the Vermont Constitution, imposes, or has the potential to impose, additional obligations on companies that collect, store, use, retain, disclose, transfer and otherwise process confidential, sensitive and personal information, and will continue to shape the data privacy environment nationally. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which could significantly harm our business, financial condition, results of operations and prospects. Further, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with such requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

We are subject to U.S. and certain foreign export control, import, sanctions, anti-corruption, and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with the laws and regulations described above could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, however this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Our employees, independent contractors, CROs, consultants, commercial partners, vendors and principal investigators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, commercial partners, vendors and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters which outline the terms of employment with each of our executive officers, each of them may terminate their employment with us at any time. As such, these employment offer letters do not guarantee our retention of our executive officers for any period of time. We do not maintain "key person" insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. We are based in the Cambridge area of Boston, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business, prospects, financial condition and results of operations.

We expect to grow our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of March 31, 2022, we had 42 employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs, finance and, if any of our product candidates receive marketing approval, sales, marketing and distribution. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of

additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy.

We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, inability to access systems, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality, availability and integrity of such confidential information. Our internal information technology systems and infrastructure, and those of our contractors, consultants, vendors and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, intentional or accidental actions or inactions by persons inside our organization or by persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, supply chain attacks foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. As a result of the COVID-19 pandemic, we may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs.

Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws, as applicable, such as HIPAA, CCPA, HITECH and GDPR), it could result in a material disruption of our discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, any of which could materially adversely affect our business, results of operations and financial condition.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

We depend on our employees, consultants, contract manufacturers, and CROs, and other parties, for the continued operation of our business. Our or their operations could be significantly disrupted by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, ice and snowstorms, extreme weather conditions, medical epidemics or pandemics, terrorist attacks, and other natural or manmade disasters or business interruptions, for which we are, and they may be, predominantly self-insured. Because we rely on third-party contract manufacturers to produce our product candidates, our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

A variety of risks associated with marketing our product candidates internationally, if approved, could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- regulatory requirements in foreign countries that differ from those in the United States;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may not continue to develop or be sustained and our stockholders may not be able to resell their shares of our common stock.

Our common stock began trading on the Nasdaq Global Select Market on April 30, 2021. Prior to April 30, 2021, there was no public market for our common stock. We cannot predict the extent to which an active market for our common stock will continue to develop or be sustained, or how the development of such a market might affect the market price for our common stock. As a result, it may be difficult for our stockholders to sell their shares of our common stock at an attractive price or at all.

The price of our common stock could be subject to volatility related or unrelated to our operations.

Our stock price is likely be volatile. For example, from April 30, 2021, when our stock first began trading on Nasdaq until May 6, 2022, our stock price has ranged from $3.51 to $21.67. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at an attractive price or at all. The market price for our common stock may be influenced by many factors, including:

- adverse results from preclinical studies;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in initiating or completing, or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- clinical trial results from, or regulatory approval of, a competitor's product candidate;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;

- introduction of new products or services by our competitors;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- our cash position;
- sales of our common stock by us or our stockholders in the future;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology and pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws or pharmaceutical pricing in the United States or foreign jurisdictions, or speculation regarding such changes;
- developments with respect to the COVID-19 pandemic;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If securities or industry analysts do not publish or cease publishing research or reports about our company, or if they issue unfavorable or inaccurate research regarding our business, our share price and trading volume could decline.

The trading market for our common stock relies, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have research control over these analysts. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analysts with provide favorable coverage. Although we have obtained coverage, if one or more of the analysts covering us downgrades our stock or publishes unfavorable or inaccurate research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our principal stockholders and management own a significant percentage of our common stock and will be able to exert significant control over matters subject to stockholder approval.

As of May 6, 2022, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned in the aggregate approximately 51.7% of our outstanding common stock.

As a result of their share ownership, these stockholders, if they act together, have the ability to influence our management and policies and are able to significantly affect the outcome of matters requiring stockholder approval such as elections of directors, amendments of our organizational documents or approvals of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;

- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We have broad discretion regarding use of our cash and cash equivalents, and we may use them in ways that do not enhance our operating results or the market price of our common stock.

Our management has broad discretion in the application of our cash and cash equivalents. We could utilize our cash and cash equivalents in ways our stockholders may not agree with or that do not yield a favorable return, if any, and our management might not apply our cash and cash equivalents in ways that ultimately increase the value of our stockholders' investments. If we do not utilize our cash and cash equivalents in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not previously incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, Nasdaq listing requirements, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel have and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements and will make some activities more time-consuming and costly compared to when we were a private company.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our filing of an Annual Report on Form 10-K with the SEC for the year ending December 31, 2022. However, while we remain an emerging growth company or a smaller reporting company with less than $100.0 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

In the past, we identified material weaknesses in our internal control over financial reporting, all of which have since been remediated. We did not identify any material weakness as of December 31, 2021.

If in the future, we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the Securities and Exchange Commission, or SEC, under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. As discussed above, we have identified material weaknesses in the past which have since been remediated. However, our remediation of previous material weaknesses may not prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company under the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012 or a smaller reporting company with less than $100.0 million in annual revenue, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal control over financial reporting, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us

for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees and increase the costs to our stockholders of bringing such claims.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, and increase the costs to such stockholders of bringing such a claim, either of which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find the either exclusive forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and operating results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from Registered Securities

On May 4, 2021, we closed our initial public offering, or IPO, of common stock under a registration statement on Form S-1 (File No. 333-255132) that was declared effective on April 29, 2021. Information related to our intended use of the proceeds from our IPO is included in the "Use of Proceeds" section of the final prospectus dated April 29, 2021, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act. There has been no material change in the planned use of proceeds from our IPO as described in the final prospectus.

As of March 31, 2022, we have used approximately $46.4 million of the net proceeds from the IPO.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on May 5, 2021).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on May 5, 2021).
10.1*^	Collaboration and License Agreement dated as of April 6, 2022 by and between the Registrant and Jazz Pharmaceuticals Ireland Limited.
10.2	Amended and Restated Loan and Security Agreement dated as of April 12, 2022, by and between the Registrant and Pacific Western Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 15, 2022.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith

^ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

† The certifications attached as Exhibit 32.1 that accompany this Quarterly Report, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Werewolf Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

WEREWOLF THERAPEUTICS, INC.

Date: May 10, 2022

By: /s/ Timothy W. Trost
Timothy W. Trost
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 10.1

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

COLLABORATION AND LICENSE AGREEMENT

by and between

Jazz Pharmaceuticals Ireland Limited

and

Werewolf Therapeutics, Inc.

Dated as of April 6, 2022

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this "**Agreement**") is entered into as of April 6, 2022 (the "**Effective Date**"), by and between **Jazz Pharmaceuticals Ireland Limited**, a corporation organized under the laws of Ireland with its principal place of business at Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland ("**Jazz**"), and **Werewolf Therapeutics, Inc.**, a corporation organized under the laws of the State of Delaware with its principal place of business at 1030 Massachusetts Avenue, Suite 210, Cambridge, MA 02138 ("**Werewolf**"). Jazz and Werewolf are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

Recitals

Whereas, Werewolf is engaged in the development of oncology therapeutic products that incorporate its proprietary INDUKINE technology (as further described herein);

Whereas, Jazz is engaged in the development and commercialization of pharmaceutical products;

Whereas, Jazz desires to obtain an exclusive license to Exploit (as defined below) Licensed Products (as defined below) and wishes to engage Werewolf to perform on Jazz's behalf certain pre-clinical development activities, and Werewolf desires to grant such license to Jazz and perform such activities, on the terms and conditions set forth in this Agreement.

Now, Therefore, in consideration of the mutual representations, warranties, and covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto hereby agree as follows:

Agreement

1. Definitions

The terms in this Agreement with initial letters capitalized, have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1.1 "**Acquirer**" shall mean the Person or group of Persons acting in concert that acquire control (whether by asset purchase, merger, consolidation, reorganization or otherwise) of a Party in a Change of Control transaction or transactions.

1.2 "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" and, with correlative meanings, the terms "controlling", "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a

limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management or policies of such entity.

1.3 "**Alliance Manager**" has the meaning set forth in Section 2.9.

1.4 "**Annual Net Sales**" means the total Net Sales of all Licensed Products in a particular Calendar Year or, with respect to the Calendar Year that includes the First Commercial Sale, the period beginning on such date of First Commercial Sale through the end of the Calendar Year in which such sale occurred. Notwithstanding the foregoing, Annual Net Sales shall only include Net Sales of Licensed Products in countries in which the Royalty Term for such Licensed Product in such country has not expired.

1.5 "**Applicable Law**" means any multinational, supranational, federal, state, local, municipal, foreign, or other law, statute, legislation, constitution, principle of common law, resolution, ordinance, code, edict, decree, proclamation, treaty, convention, rule, regulation, ruling, directive, pronouncement, requirement, specification, determination, decision, opinion, or interpretation issued, enacted, adopted, passed, approved, promulgated, made, implemented, or otherwise put into effect by or under the authority of any Governmental Body that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.

1.6 "**Auditor**" has the meaning set forth in Section 12.2.

1.7 "**Business Day**" means 9.00am to 5.00pm local time on a day (other than a Saturday, Sunday, or a public holiday) on which the banks are open for business in Dublin, Ireland, Cambridge, Massachusetts and New York, New York.

1.8 "**Calendar Quarter**" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31. For the avoidance of doubt, the first Calendar Quarter shall commence on the Effective Date, and the final Calendar Quarter shall end on the effective date of the expiration or termination of this Agreement.

1.9 "**Calendar Year**" means each respective period of twelve (12) consecutive months ending on December 31. For the avoidance of doubt, the first Calendar Year shall commence on the Effective Date, and the final Calendar Year shall end on the effective date of the expiration or termination of this Agreement.

1.10 "**Centralized Procedure**" means the procedure through which a Drug Approval Application filed with the EMA results in a single marketing authorization valid throughout the European Union.

1.11 "**cGLP**" means current good laboratory practice standards, practices and procedures required, promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58

(or such other comparable regulatory standards in jurisdictions outside the U.S.), as may be amended from time to time.

1.12 "**cGMP**" means all good manufacturing practices under Title 21 of the United States Code of Federal Regulations, as amended from time to time and comparable laws and regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.13 "**Change of Control**" shall mean, with respect to a Person: (a) the sale of all or substantially all of such Person's assets or business; (b) a merger, reorganization or consolidation involving such Person in which the voting securities of such Person outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a Person, or group of Persons acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Person.

1.14 "**Clinical Trial**" means any one or combination of a Phase 1 Clinical Trial, Phase 2 Clinical Trial, or Phase 3 Clinical Trial, as the context dictates.

1.15 "**Combination Product**" means a Licensed Product containing or consisting of one (1) or more Licensed Compounds and one (1) or more Other Active Ingredients, whether in the same or different formulations.

1.16 "**Commercialize**," means any and all activities related to pre-marketing, launching, marketing, promotion (including advertising and detailing), labelling, bidding and listing, obtaining pricing and reimbursement approval, distribution, storage, handling, offering for sale, selling, having sold, importing, having imported, exporting, having exported, distributing, having distributed, providing customer service and support, conducting medical affairs, conducting post-marketing safety surveillance, and reporting of or otherwise commercializing or exploiting Licensed Compounds or Licensed Products. "**Commercialization**" has the correlative meaning with respect to such activities.

1.17 "**Commercially Reasonable Efforts**" means, with respect to the performance of Development or Commercialization activities with respect to a Licensed Compound or Licensed Product, [**]. For this purpose, [**].

1.18 "**Confidential Information**" has the meaning set forth in Section 14.1 of this Agreement.

1.19 "**Confidentiality Agreement**" means that certain Mutual Confidential Disclosure Agreement between the Parties [**], as may be amended from time to time, including that certain Amendment No. 1 dated and effective as of [**], that certain Amendment No. 2 dated and effective as of [**], and that certain Amendment No. 3 dated and effective as of [**].

1.20 "**Control**" or "**Controlled**" means, with respect to any item of Information, material, Patent, or other property right, the possession of the right, whether directly or indirectly, and whether by ownership or license (other than by operation of the license and other

grants in this Agreement), to grant a license, sublicense, access or other right to or under such Information, material, Patent, or other property right as provided for herein.

1.21 "**Cost of Goods**" means, with respect to any Licensed Compounds or Licensed Products supplied pursuant to this Agreement, and without duplication: (a) to the extent the Licensed Compound or Licensed Product is manufactured by the supplying Party or its Affiliates, such Party's or such Affiliate's [**], including: (i) direct material costs [**]; (ii) direct labor costs [**] of [**]; (iii) costs [**] of [**] activities; (iv) [**] costs; and (v) [**], all of the foregoing determined in accordance with GAAP consistently applied; and (b) to the extent Licensed Compound or Licensed Product is manufactured by a Third Party contract manufacturing organization, (1) [**], including (i) costs for [**], provided that [**], and (ii) other costs [**], to the extent such costs [**], and (2) the supplying Party's direct labor costs for [**]. Notwithstanding the foregoing, to the extent Licensed Compound or Licensed Product is manufactured by a Party or its Affiliates, Cost of Goods will not include any [**].

1.22 "**Cover**" or "**Covered**" means, with respect to a particular subject matter at issue and a relevant Patent, that, in the absence of ownership of or a license under such Patent, the manufacture, use, sale, offer for sale, or importation of such subject matter would infringe one or more Valid Claims of such Patent, or, as to a pending claim included in such Patent, the manufacture, use, sale, offer for sale, or importation of such subject matter would infringe such Patent if such pending claim were to issue in an issued patent, provided that such claim is being prosecuted in good faith.

1.23 "**Cytokine**" means any chemokine, interferon, interleukin, lymphokine, or growth factor.

1.24 "**Damages**" means any loss, damage, diminution in value, claim, demand, settlement amount, judgment, award, fine, penalty, and reasonable costs and expenses of legal proceedings (including reasonable legal fees, expert fees, accounting fees or advisory fees).

1.25 "**Development**" means all activities related to pre-clinical, non-clinical, and clinical drug discovery, research, or development activities, test method development and stability testing, toxicology, Licensed Compound manufacturing process development, CMC activities, formulation process development, manufacturing scale-up, qualification and validation, including quality assurance and quality control development, and any other activities reasonably related to or intended to lead to manufacture and supply of Licensed Compounds and Licensed Products, and the development and submission of information to a Regulatory Authority. When used as a verb, "**Develop**" means to engage in Development. For the avoidance of doubt, Development shall include any submissions (and activities required in support thereof) required by Applicable Laws or a Regulatory Authority as a condition or in support of obtaining a pricing or reimbursement approval for an approved molecule or product.

1.26 "**Development Budget**" has the meaning set forth in Section 6.2(a).

1.27 "**Development Plan**" means the written plan setting forth the Development activities to be performed by Werewolf with respect to any Licensed Compound or Licensed Product under this Agreement, as may be amended and updated from time to time in accordance with Section 6.2.

1.28 "**Development Records**" has the meaning set forth in Section 6.8(a).

1.29 "**Dollars**" or **"$"** means United States Dollars.

1.30 "**Drug Approval Application**" means (a) a New Drug Application, submitted to the FDA pursuant to 21 CFR § 314.50 ("**NDA**"); (b) a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act and the regulations promulgated thereunder ("**BLA**"); (c) an application for authorization to market and/or sell a biological or pharmaceutical product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., including, with respect to the European Union, a marketing authorization application filed with the EMA pursuant to the Centralized Procedure or with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure ("**MAA**"); or (d) with respect to any biological or pharmaceutical product for which a NDA, BLA or MAA has been approved by the applicable Regulatory Authority, an application to supplement or amend such NDA, BLA or MAA to expand the approved label for such biological product to include use of such biological product for an additional Indication.

1.31 "**EMA**" means the European Medicines Agency and any successor agency or authority having substantially the same function.

1.32 "**European Union**" means the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto.

1.33 "**Equivalent Product**" has the meaning set forth in Section 4.2.

1.34 "**EU Approval**" means (a) receipt of Regulatory Approval of a Licensed Product in the European Union by the Centralized Procedure or in at least one of the Major European Countries and (b) first receipt of Pricing Approval for such Licensed Product in at least one of the Major European Countries.

1.35 "**Executive Sponsors**" means, with respect to each of Werewolf and Jazz, a key executive with senior decision-making authority.

1.36 "**Exploit**" or "**Exploitation**" means to make, have made, manufacture, import, export, use, sell, offer for sale, have sold, research, Develop, Commercialize, hold or keep (whether for disposal or otherwise), transport, distribute, promote, market or otherwise dispose of.

1.37 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.38 "**FDA Approval**" means receipt of Regulatory Approval of a Licensed Product by the FDA.

1.39 "**Financial Records**" has the meaning set forth in Section 12.1.

1.40 "**First Commercial Sale**" means, with respect to a Licensed Product and a country, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such country after Regulatory Approval for the sale of such Licensed Product has been obtained in such country and where such disposition or transfer results in a recordable Net Sale in accordance with Jazz, or its Affiliate's or Sublicensee's applicable accounting practices (consistently applied). Sales prior to receipt of Regulatory Approval for such Licensed Product, such as so-called "treatment IND sales", "named patient sales", and "compassionate use sales" shall not constitute a First Commercial Sale.

1.41 "**First Indication**" means the first Indication for which any Licensed Product has (i) been studied as referenced in the applicable protocol, in relation to a Clinical Trial, or (ii) received Regulatory Approval in a particular jurisdiction (e.g., [**]).

1.42 "**Force Majeure Event**" has the meaning set forth in Section 19.12.

1.43 "**FTE**" means the equivalent of one (1) appropriately qualified full-time Werewolf (including its Affiliates) employee's work for a twelve (12) month period (consisting of a total of at least [**] hours per Calendar Year of dedicated effort). Any such employee who devotes fewer than [**] hours per Calendar Year on the applicable activities shall be treated as an FTE on a pro-rata basis, based upon the actual number of hours worked by such employee on such activities, divided by [**]. For the avoidance of doubt, only hours devoted by qualified scientific, medical, manufacturing, technical, regulatory and other similar employees of Werewolf, as measured in accordance with Werewolf's normal time allocation practices, shall apply toward an FTE, and in no event shall "FTE" include hours devoted by personnel performing administrative, managerial or corporate functions (e.g., human resources, finance, legal, and investor relations).

1.44 "**FTE Cost**" means the FTE Rate multiplied by the number of FTEs applied to the performance of the relevant activity in accordance with the applicable Development Plan.

1.45 "**FTE Rate**" means an initial rate of [**] Dollars ($[**]) per FTE per year, which rate shall apply through December 31, 2022. Thereafter, the FTE Rate shall be changed annually on a Calendar Year basis to reflect any year-to-year percentage increase or decrease (as the case may be) in the Consumer Price Index for All Urban Consumers, as published by the U.S. Department of Labor, Bureau of Labor Statistics ("**CPI**") (based on the change from the most recent CPI available as of the Effective Date to the most recent CPI available as of the date of the calculation of such revised FTE Rate). For the avoidance of doubt, the FTE Rate is intended to cover the cost of salaries, benefits, infrastructure, travel, general laboratory or general office supplies, postage, insurance, training and all other general expenses and overhead items.

1.46 "**GAAP**" means generally accepted accounting principles in the United States.

1.47 "**Generic Version**" means, with respect to a particular Licensed Product and a particular country, any pharmaceutical or biological product that: (a) is biosimilar to, or interchangeable with, such Licensed Product, may be legally substituted for such Licensed Product, or otherwise is approved under a separate Regulatory Approval and in a manner that relied on or incorporated data submitted in connection with the regulatory filings for such

Licensed Product; and (b) is sold in such country by a Person other than Jazz, its Affiliates or Sublicensees.

1.48 "**GLP Toxicology Study**" means any animal pharmacology and toxicology study conducted using cGLP.

1.49 "**Governmental Body**" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature, (b) federal, state, local, municipal, foreign or other government, (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or Person and any court or other tribunal), (d) supranational, multi-national organization or body, or (e) individual, Person, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.50 "**IFNα**" means Interferon alpha.

1.51 "**IND**" means an application filed with a Regulatory Authority for authorization to commence Clinical Trials, including (a) an Investigational New Drug Application as defined in the United States Federal Food, Drug, and Cosmetic Act and the guidelines, guidances, and requirements promulgated thereunder, (b) any equivalent of a United States IND in other countries or regulatory jurisdictions, (e.g., a Clinical Trial Application ("**CTA**")), and (c) all amendments thereof that may be filed with respect to the foregoing.

1.52 "**IND Clearance**" means, with respect to an IND, the earlier to occur of: (a) receipt by or on behalf of Jazz or any of its Affiliates or Sublicensees, of written confirmation from a Regulatory Authority that Clinical Trials may commence or be conducted under such IND; or (b) expiration of the applicable waiting period after which Clinical Trials may commence or be conducted under such IND.

1.53 "**[**]**" has the meaning set forth in Section [**].

1.54 "**IND Data Package**" has the meaning set forth in Section 6.4(a).

1.55 "**IND-Enabling Studies**" means the efficacy, genotoxicity, acute toxicology, safety pharmacology, and sub-chronic toxicology studies, that are intended to satisfy the applicable regulatory requirements, using applicable cGLP, that meet the standard necessary for submission as part of an IND.

1.56 "**Indemnitee**" has the meaning set forth in Section 16.3.

1.57 "**Indemnitor**" has the meaning set forth in Section 16.3.

1.58 "**Indication**" means a distinct disease, disorder, illness, or health condition and all of its associated signs, symptoms, or any progression of the foregoing (including precursor conditions). An Indication shall be distinct from another Indication if the two indications relate

to the prevention or treatment of diseases, disorders, illnesses, or health conditions caused or characterized by, or associated with, [**].

1.59 "**Information**" means all knowledge of a technical, scientific, business and other nature, including technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, regulatory data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, reagents (e.g., plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic, or any other form now known or hereafter developed.

1.60 "**Initial Development Plan**" means the initial Development Plan set forth in **Schedule 1.60**.

1.61 "**Initial Lead Molecule**" means that certain IFNα INDUKINE molecule referred to internally by Werewolf as WTX-613, as described in the letter from Reid Leonard, Chief Operating Officer of Werewolf, to Robert Iannone, Executive Vice President, Global Head of Research and Development of Jazz Pharmaceuticals PLC dated as of the Effective Date.

1.62 "**Initiation**", "**Initiated**" or "**Initiates**" means, with respect to a Clinical Trial, the first dosing of the first (1st) human subject in such Clinical Trial.

1.63 "**Insolvency Event**" has the meaning set forth in Section 17.4.

1.64 "**Inspector**" has the meaning set forth in Section 6.7.

1.65 "**Intellectual Property Rights**" means any work of authorship, copyright, Patents, utility models, trade secret, trademark, tradename, trade or service mark (whether or not registered or unregistered), database rights, design rights (whether or not registered or unregistered), Know-How, and any registrations or applications relating to any of the foregoing, and any other rights of a similar nature or character, whether now existing or hereafter invented, discovered, created, made, conceived, developed, arising, or otherwise coming into being, as recognized by Applicable Law.

1.66 "**IFNα-based Domain**" means (a) any naturally occurring or engineered IFNα or (b) any amino acid sequence variant thereof that (i) binds the type I IFN receptor and (ii) activates type I IFN receptor mediated signal transduction.

1.67 "**Jazz Background Know-How**" means any and all Know-How Controlled by Jazz or any of its Affiliates (a) as of the Effective Date or (b) during the Term that is developed or invented through efforts outside of this Agreement.

1.68 "**Jazz Background Patents**" means any and all Patents Controlled by Jazz or any of its Affiliates on the Effective Date or during the Term that Cover any Jazz Background Know-How.

1.69 "**Jazz Development Activities**" has the meaning set forth in Section 6.1.

1.70 "**Jazz Development IP**" means the Jazz Development Know-How and Jazz Development Patents.

1.71 "**Jazz Development Know-How**" means any and all Know-How that is developed or invented: (a) between [**] and the Effective Date, by or on behalf of Werewolf or its Affiliates in the course of performing Development activities with respect to the Initial Lead Molecule, provided that such Know-How is not Werewolf Development Know-How, (b) during the Term, by or on behalf of a Party or its Affiliates, or by or on behalf of both Parties or their Affiliates jointly, in each case in the course of performing any Werewolf Development Activities, provided that such Know-How is not Werewolf Development Know-How, or (c) during the Term, solely by or on behalf of Jazz or its Affiliates in the course of performing activities directly related to the Exploitation of one or more Licensed Products.

1.72 "**Jazz Development Patents**" means any and all Patents Controlled by Jazz on or after the Effective Date that Cover Jazz Development Know-How.

1.73 "**Jazz Development Plan**" means the written plan submitted by Jazz to the JSC and finalized by Jazz pursuant to Section 6.11(a), as such plan may be amended and updated from time to time in accordance with Section 6.11(b).

1.74 "**Jazz Indemnitees**" means the following Persons: (a) Jazz; (b) Jazz's current and future Affiliates; (c) the respective Representatives of the Persons referred to in clauses (a) and (b) above; and (d) the respective successors and permitted assigns of the Persons referred to in clauses (a), (b), and (c) above.

1.75 "**Jazz Polypeptide**" has the meaning set forth in Section 1.79(c).

1.76 "**Joint Steering Committee**" or the "**JSC**" has the meaning set forth in Section 2.1.

1.77 "**Key Personnel**" has the meaning set forth in Section 6.5.

1.78 "**Know-How**" means any and all data, results, inventions, methods, processes, trade secrets, techniques, technology, and other proprietary Information, whether patentable or not but which are not generally known, including discoveries, formulae, materials (including chemicals), biological materials (including expression constructs, assays, animal models, nucleic acid sequences, amino acid sequences, and cell lines), practices, test data (including pharmacological, toxicological, pre-clinical and clinical information and test data), analytical and quality control data (including drug stability data), manufacturing technology and data (including formulation data), and sales forecasts, data and descriptions.

1.79 "**Licensed Compound**" means:

(a) the Initial Lead Molecule,

(b) subject to Section 5.1, any isolated recombinant polypeptide that is identified, developed, synthesized, created, discovered, generated or invented by or on behalf of Werewolf or its Affiliates prior to the Effective Date or during the Term and that comprises at least one of each of the following domains (i) an IFNα-based Domain, [**]; such polypeptide may also comprise one or more additional domains, including one or more [**] domains but may not comprise any [**] domains other than [**]; or

(c) any isolated recombinant polypeptide that is identified, developed, synthesized, created, discovered, generated or invented by or on behalf of Jazz or its Affiliates during the Term using the Licensed Technology and that comprises at least one of each of the following domains: (i) an IFNα-based Domain, [**]; such polypeptide may also comprise one or more additional domains, including one or more [**] domains but may not comprise any [**] domains other than [**] (each such polypeptide, a "**Jazz Polypeptide**");

each of (b)-(c) solely to the extent that [**] of the recombinant polypeptide [**].

1.80 "**Licensed Know-How**" means the Werewolf Development Know-How and the Werewolf Background Know-How.

1.81 "**Licensed Patents**" means the Werewolf Development Patents and the Werewolf Background Patents.

1.82 "**Licensed Product**" means any product that contains one (1) or more Licensed Compounds, whether alone or together with one (1) or more Other Active Ingredients, in any dosage strength, form, or formulation, and for any mode of administration. For the avoidance of doubt, all Licensed Products that contain the same Licensed Compound shall be considered to be the same Licensed Product, whether or not with Other Active Ingredients, and whether or not they are in a different pharmaceutical form, formulation, dosage form, dosage strength, or which have a different mode of delivery, and for such purposes, all Licensed Compounds that have the same domains shall be considered to be the same Licensed Compound.

1.83 "**Licensed Product Improvement Fee**" has the meaning set forth in Section 5.1(c)(ii).

1.84 "**Licensed Product Improvement Test Data**" means data arising from the testing of (a) a New Domain that is an IFNα-based Domain or (b) a New Domain together with an IFNα-based Domain, which data can be used to determine whether such New Domain could result in a Licensed Compound that [**].

1.85 "**Licensed Technology**" means the Werewolf Background IP and Werewolf Development IP.

1.86 "**Mainland China**" means the People's Republic of China; it does not include Hong Kong or Taiwan.

1.87 "**Major European Country**" means any of [**].

1.88 "**Major Market Country**" means any of [**].

1.89 "**Milestone Event**" means a milestone event described in a table set forth in Section 10.2 or 10.3.

1.90 "**Milestone Payment**" means a milestone payment described in a table set forth in Section 10.2 or 10.3.

1.91 "**Net Sales**" means, with respect to a Licensed Product, the total amounts received by Jazz, its Affiliates, or Sublicensees in the Territory from sales of such Licensed Product to Third Parties, in *bona fide* arm's length transactions, less customary deductions, to the extent that they are in accordance with the standard internal policies and procedures consistently applied by that party recording such sales to calculate revenue for financial reporting purposes, including deductions actually taken, paid, accrued, allocated or allowed based on good faith estimates, with respect to such sales (and consistently applied) including:

(a) [**];

(b) [**];

(c) [**];

(d) [**];

(e) [**];

(f) [**];

(g) [**]; and

(h) [**].

For clarity, Net Sales shall not include [**] or [**]. Further, [**] shall be disregarded in determining Net Sales. Net Sales shall not include sales between or among Jazz, its Affiliates, or Sublicensees.

For purposes of calculating Net Sales, all Net Sales shall be converted into Dollars in accordance with Section 11.1.

In the event a Licensed Product is a Combination Product, the Net Sales for such Combination Product shall be calculated as follows:

(i) If Jazz, its Affiliate, or Sublicensee separately sells in such country or other jurisdiction, (A) a product containing as its sole active ingredient a Licensed Compound contained in such Combination Product (the "**Mono Product**") and (B) products containing as their sole active ingredients the Other Active Ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where: "A" is [**] and "B" is [**].

(ii) If Jazz, its Affiliate, or Sublicensee separately sells in such country or other jurisdiction the Mono Product but does not separately sell in such country or other jurisdiction products containing as their sole active ingredients the Other Active Ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying the Net Sales of such Combination Product by the fraction A/C where: "A" is [**], and "C" is [**].

(iii) If Jazz, its Affiliates, and Sublicensees do not separately sell in such country or other jurisdiction the Mono Product but do separately sell products containing as their sole active ingredients the Other Active Ingredients contained in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying the Net Sales of such Combination Product by the fraction (D-E)/D where: "D" is the [**] and "E" is the [**].

(iv) If Jazz, its Affiliates, and Sublicensees do not separately sell in such country or other jurisdiction both the Mono Product and the Other Active Ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be determined by [**].

1.92 "**New Domain**" has the meaning set forth in Section 5.1(b).

1.93 "**New Third Party IP**" has the meaning set forth in Section 5.1(c)(ii).

1.94 "**New Third Party IP Payment**" has the meaning set forth in Section 5.1(c)(ii).

1.95 "**Other Active Ingredient**" means any active ingredient in a Combination Product which is not a Licensed Compound, but excluding [**].

1.96 "**Patents**" means: (a) all national, regional and international patents and patent applications, including provisional patent applications and any and all rights to claim priority thereto; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.97 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department, or agency of a government.

1.98 "**Phase 1 Clinical Trial**" means a human clinical trial of a Licensed Product that satisfies the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.99 "**Phase 2 Clinical Trial**" means (a) a human clinical trial of a Licensed Product that satisfies the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations), regardless of where such clinical trial is conducted; provided that (b) [**], and (c) [**].

1.100 "**Phase 3 Clinical Trial**" means a human clinical trial of a Licensed Product that satisfies the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), regardless of where such clinical trial is conducted, and is designed to ascertain efficacy and safety of such Licensed Product for the purpose of submitting a Drug Approval Application to a Regulatory Authority.

1.101 "**Phase 1 Delivery Schedule**" has the meaning set forth in Section 8.2(b).

1.102 "**Plan Revisions**" has the meaning set forth in Section 6.2(b).

1.103 "**Pricing Approval**" means such governmental approval, agreement, determination, or decision establishing prices for a Licensed Product that can be charged and/or reimbursed in regulatory jurisdictions where the applicable Regulatory Authorities approve or determine the price and/or reimbursement of pharmaceutical products.

1.104 "**Product Patents**" means any Werewolf Background Patent or Werewolf Development Patent that solely claims the composition of matter, manufacture, or method of use of one or more Licensed Compounds or Licensed Products.

1.105 "**Project Manager**" has the meaning set forth in Section 2.8.

1.106 "**Proposal Budget**" means the budget for the Werewolf Reimbursable Costs between [**] and the Effective Date, as set out in **Schedule 1.106**.

1.107 "**Regulatory Approval**" means, with respect to any Licensed Product, any and all approvals (including NDAs and supplements and amendments thereto and active INDs), licenses, registrations (except manufacturing establishment registrations) or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market any Licensed Product, including, where applicable, (a) Pricing Approval, (b) pre- and post-approval marketing authorizations, and (c) labeling approvals.

1.108 "**Regulatory Authority**" means any applicable Government Body responsible for granting Regulatory Approvals for any product, including the FDA and EMA.

1.109 "**Representatives**" means officers, directors, employees, agents, attorneys, accountants, advisors, consultants, and representatives.

1.110 "**Rest of the Territory**" means the Territory excluding [**].

1.111 "**Royalty Term**" means, with respect to each Licensed Product and each country in the Territory, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country, and ending on the latest to occur of (a) the expiration of the last-to-expire Valid Claim of any Licensed Patent that Covers the composition of matter of the Licensed Compound contained in such Licensed Product in such country, (b) the [**] anniversary of the First Commercial Sale of such Licensed Product in such country, and (c) the expiration of regulatory exclusivity (including pursuant to 42 U.S.C. §262(k)(7)(A) if applicable) for such Licensed Product in such country.

1.112 "**Second Indication**" means, with respect to a particular milestone event (e.g. FDA Approval), any Indication other than the First Indication for which such milestone event was achieved by Jazz or its Affiliate or Sublicensee with respect to any Licensed Product.

1.113 "**Service Taxes**" has the meaning set forth in Section 11.3(a).

1.114 "**Subcontractor Background IP**" means any Intellectual Property Rights that (a) are Controlled by a Third-Party subcontractor prior to its engagement by Werewolf to perform Werewolf Development Activities or independent of such engagement and (b) are necessary to Exploit any Intellectual Property Rights generated by such subcontractor in the course of performing the subcontracted Werewolf Development Activities.

1.115 "**Subcontractor Improvement IP**" has the meaning set forth in Section 6.6.

1.116 "**Sublicensee**" means any Third Party that is sublicensed under the Licensed Technology by Jazz to Exploit or have Exploited Licensed Compounds or Licensed Products, excluding any wholesaler, distributor, or other contractor under Section 3.3.

1.117 "**Tax**" means any tax (including any income tax, franchise tax, capital gains tax, estimated tax, gross receipts tax, value-added tax, surtax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, occupation tax, inventory tax, occupancy tax, withholding tax or payroll tax), levy, assessment, tariff, impost, imposition, toll, duty (including any customs duty), deficiency or fee, and any related charge or amount (including any fine, penalty or interest), that is, has been or may in the future be imposed, assessed or collected by or under the authority of any Governmental Body.

1.118 "**Term**" has the meaning set forth in Section 17.1.

1.119 **"Territory"** means worldwide.

1.120 **"Third Indication"** means, with respect to a particular milestone event (e.g. FDA Approval), any Indication other than the First Indication or the Second Indication for which such milestone event was achieved by Jazz or its Affiliate or Sublicensee with respect to any Licensed Product.

1.121 "**Third Party**" means any Person other than Jazz or Werewolf or an Affiliate of either Jazz or Werewolf.

1.122 "**Third Party Claim**" has the meaning set forth in Section 16.1.

1.123 "**United States**" means the United States of America, including its territories and possessions.

1.124 "**Valid Claim**" means either: (a) a claim of a pending Patent application that has not been pending for more than [**] after the relevant application date for said application, which claim was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application; or (b) a claim of any issued and unexpired Patent for which the validity, enforceability, or patentability has not been affected by any of the following: (x) irretrievable lapse, cancellation, abandonment, revocation, dedication to the public, or disclaimer; or (y) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction without the possibility of appeal. A claim that was pending for more than [**] after the relevant application date for said application and that subsequently issues in a granted Patent shall, subject to this Section 1.124(b), be considered a Valid Claim as of such subsequent issuance date, [**].

1.125 "**Werewolf Background IP**" means the Werewolf Background Know-How and the Werewolf Background Patents.

1.126 "**Werewolf Background Know-How**" means any and all Know-How Controlled by Werewolf or any of its Affiliates (a) on the Effective Date (except to the extent that such Know-How is Jazz Development Know-How pursuant to Section 1.71(a)), or (b) during the Term that is developed or invented through efforts outside of this Agreement, in each case (a) and (b), that is necessary or reasonably useful to Exploit Licensed Compounds or Licensed Products. The Werewolf Background Know-How includes all Know-How listed on **Schedule 1.125.** For clarity, and subject to the foregoing, the Werewolf Background Know-How does not include any Know-How Controlled by Werewolf or any of its Affiliates that (i) is solely related to Werewolf's INDUKINE technology, (ii) was or is not used by Werewolf or any of its Affiliates with respect to the Initial Lead Molecule or in the course of performing Werewolf Development Activities and (iii) is not necessary or reasonably useful for the subsequent research, development, manufacture or commercialization of any Licensed Compound or Licensed Product.

1.127 "**Werewolf Background Patents**" means (a) the Patents set forth in **Schedule 1.126**; and (b) any Patents Controlled by Werewolf and/or any of its Affiliates (i) as of the Effective Date, or (ii) during the Term that are invented through efforts outside of this Agreement, in each case (i) and (ii) that Cover any Werewolf Background Know-How or the composition of matter, manufacture, method of use, formulation or other use of any Licensed Compound or Licensed Product or any component thereof.

1.128 "**Werewolf Development IP**" means the Werewolf Development Patents and Werewolf Development Know-How.

1.129 "**Werewolf Development Know-How**" means any and all Know-How that (a) is developed or invented (i) between [**] and the Effective Date, by or on behalf of Werewolf or its Affiliates in the course of performing Development activities with respect to the Initial Lead Molecule, or (ii) during the Term, by or on behalf of Werewolf or its Affiliates in the course of performing the Werewolf Development Activities and (b)(i) [**], or (ii) [**].

1.130 "**Werewolf Development Patents**" means any and all Patents Controlled by Werewolf after the Effective Date that Cover any Werewolf Development Know-How.

1.131 "**Werewolf Development Activities**" has the meaning set forth in Section 6.1.

1.132 "**Werewolf In-License**" means any agreement existing on the Effective Date or which comes into effect during the Term pursuant to which Werewolf or any of its Affiliates are granted rights which form part of the Licensed Technology.

1.133 "**Werewolf Indemnitees**" means the following Persons: (a) Werewolf; (b) Werewolf's current and future Affiliates; (c) the respective Representatives of the Persons referred to in clauses (a) and (b) above; and (d) the respective successors and permitted assigns of the Persons referred to in clauses (a), (b) and (c) above.

1.134 "**Werewolf Reimbursable Costs**" means (a) all external pass-through costs and FTE Costs reasonably actually incurred by Werewolf between [**] and the Effective Date which arose directly and specifically from the performance by Werewolf of Development activities with respect to the Initial Lead Molecule, without in the case of pass-through costs, any handling fee, administration fee or other form of mark-up, provided that such costs do not exceed the Proposal Budget, and (b) all external pass-through costs and FTE Costs reasonably actually incurred by Werewolf during the Term which arose directly and specifically from the performance by Werewolf of Werewolf Development Activities in accordance with a Development Plan, without in the case of pass-through costs, any handling fee, administration fee or other form of mark-up, provided that such costs do not exceed the Development Budget for such activities set out in the applicable Development Plan.

1.135 "**Werewolf's INDUKINE Technology**" means Werewolf's technology for designing, optimizing and engineering conditionally activated immunomodulators to deliver cytokines that have full biological potency, by integrating specialized cytokine domains, protease-cleavable linkers, cytokine blocking domains (that can be steric blockers or specific blockers) and optionally half-life extension domains into a molecule that is administered systemically, but activated in the tissue microenvironment with a goal of generating a potent immune response while minimizing toxicity.

2. Governance

2.1 Joint Steering Committee. Within [**] after the Effective Date, or as mutually agreed to by the Parties, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**").

2.2 Specific Responsibilities of the JSC. The JSC shall oversee the Werewolf Development Activities and serve as an information sharing body with respect to Jazz Development Activities. Without limiting the foregoing, the JSC shall:

(a) foster a collaborative relationship between the Parties;

(b) review, discuss, and approve each Development Plan (other than the Initial Development Plan) and the corresponding Development Budget, in accordance with Section 6.2;

(c) review, discuss, and approve all Plan Revisions, including to the Initial Development Plan;

(d) oversee the conduct of each Development Plan;

(e) oversee the manufacturing technology transfer process set out in Section 8.7;

(f) review and discuss the results of all work conducted under any Development Plan;

(g) establish and oversee the process for the ongoing transfer of Licensed Know-How to Jazz;

(h) review and discuss the Jazz Development Plan, and any proposed annual revisions or updates;

(i) review and discuss the material results of Jazz Development Activities;

(j) establish a Patent Working Group to review and discuss the prosecution strategy for Product Patents, as set forth more fully in Section 13.1;

(k) on an as-needed basis, establish subcommittees to perform specific duties of the JSC, direct each such subcommittee to perform the functions for which it is established, and oversee each subcommittee, including resolution of disputes raised to the JSC by any subcommittee; and

(l) perform such other functions as appropriate to further the purposes of the performance of any Development Plan, as expressly set forth in this Agreement or allocated to it by the Parties' written agreement.

2.3 JSC Membership and Meetings.

(a) JSC Representatives. The JSC shall consist of [**] representatives from each Party. Each JSC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. Each Party may replace its representatives on the JSC on written notice to the other Party. [**] shall appoint the chairperson of the JSC. The chairperson shall prepare and circulate agendas to JSC members at least [**] before each JSC meeting and shall direct the preparation of reasonably detailed minutes for each JSC meeting, which shall be circulated to JSC members for review and approval within [**] after such meeting.

(b) Meetings. The JSC shall hold meetings at such times as it elects to do so, but in no event less frequently than [**] by telephone or video conference, unless otherwise agreed by the Parties. The first JSC meeting shall be held within [**] after the Effective Date. In-person meetings, if any, will be held at locations agreed by the Parties. If agreement cannot be reached then the Parties shall alternate the location of such in-person meetings, beginning with a location chosen by [**]. Each Party shall be responsible for all of its own expenses of

participating in any JSC meeting. No action taken at any meeting of the JSC shall be effective unless at least one (1) representative of each Party is participating. In addition, either Party may request that a special *ad hoc* meeting of the JSC be convened for the purpose of reviewing or making decisions pertaining to time-sensitive subject-matter, at such time as may be mutually agreed by the Parties.

(c) Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its JSC representatives, to attend the JSC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide reasonable prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld, conditioned, or delayed. Such Party shall ensure that such Third Party is bound by written confidentiality obligations consistent with the terms of this Agreement.

2.4 Decision-Making.

(a) General. During the performance of any Development Plan, the Parties shall use good faith efforts to reach all JSC decisions by consensus, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter, the representatives of the Parties cannot reach an agreement as to such matter, then either Party at any time may refer such issue to the Executive Sponsors for resolution, who shall confer in good faith. Any final decision mutually agreed by the Executive Sponsors shall be conclusive and binding on the Parties.

(b) Decision-Making Authority. If the Executive Sponsors cannot reach consensus on an issue within [**] of such issue first being referred to them, then:

(i) Werewolf shall have final decision-making authority on matters relating solely to the [**]; and

(ii) Jazz shall have final decision-making authority on all other matters within the scope of the JSC's authority, including (1) [**], and (2) [**]. Werewolf acknowledge and agrees that it [**].

2.5 Limitations on Authority. The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, the JSC shall not have the power to amend, interpret, or waive compliance with this Agreement, and no JSC decision may be in contravention of any terms and conditions of this Agreement.

2.6 Discontinuation of the JSC. The activities to be performed by the JSC shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. The JSC shall continue to exist until the first to occur of: (a) the Parties mutually agree in writing to disband the JSC or (b) [**]. Upon the first to occur of the foregoing (a) or (b), the Parties shall schedule a final JSC meeting to conclude the business of the JSC. At the conclusion of such final JSC meeting the JSC shall automatically dissolve and, thereafter, each Party shall designate, to the extent necessary, a contact person for the exchange of

information under this Agreement or such exchange of information shall be made through the designated strategic partnership managers or Alliance Managers, and decisions of the JSC, if any, shall be decisions as between the Parties, subject to the other terms and conditions of this Agreement.

2.7 Working Group. The JSC shall establish and delegate duties to a working group ("**Working Group**") to oversee the Werewolf Development Activities. Unless otherwise agreed, all communications between Jazz and Werewolf regarding the conduct of the Werewolf Development Activities shall be addressed between the Parties via the Working Group. Meetings of the Working Group shall take place as provided for in **Schedule 2.7**. The Working Group constitution, representation and frequency of meetings shall be determined in accordance with **Schedule 2.7** unless the Parties agree otherwise. Working Group meetings will be held by means of telecommunications or video conference as provided for in **Schedule 2.7**, or otherwise as the Working Group deems necessary or appropriate. Any decisions of the Working Group shall be made in the manner provided for in **Schedule 2.7**. Any dispute between the designees of Werewolf and Jazz on a Working Group shall be referred to the JSC for resolution. The Working Group shall be subject to the oversight of and direction from the JSC as set forth in **Schedule 2.7**, and shall report to the JSC. In no event shall the authority of the Working Group exceed that specified for the JSC.

2.8 Project Managers. Werewolf and Jazz shall each appoint one of its representatives on the Working Group to oversee contact between the Parties for all matters under this Agreement (each a "**Project Manager**"). The Werewolf Project Manager shall regularly report to Jazz via the Working Group and JSC on the progress and performance of the Werewolf Development Activities, including requesting that the Working Group meet to discuss various aspects of each Development Plan. Without limiting the generality of the foregoing, the Project Manager shall be permitted to call *ad hoc* meetings of the Working Group to discuss (a) performance or unavailability of a subcontractor, (b) use of replacement or alternative subcontractor, (c) issues with experiment or study design, (d) proposed Plan Revisions in light of the experimental results, and (e) other potential delays against Development Plan timelines. Each Party shall, and shall cause its Project Manager to, use commercially reasonable efforts to respond to any communication from the other Party within [**] after his/her receipt of such communication. Each Party may replace its Project Manager at any time by written notice to the other Party.

2.9 Alliance Manager. Promptly after the Effective Date, each Party shall appoint an individual who shall be an employee of such Party having appropriate seniority and experience to act as the alliance manager for such Party (the "**Alliance Manager**"). Without limiting the foregoing, each Party's Alliance Manager shall have greater seniority and experience than its Project Manager. Each Alliance Manager shall be responsible for coordinating and managing business processes and interfacing between the Parties throughout the performance of the Development Plan. Each Alliance Manager shall, in cooperation with the chairperson of the JSC, be responsible for planning and executing each JSC meeting and shall attend JSC meetings as appropriate as non-voting participants. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Party shall bear its own costs of its Alliance Manager.

3. License

3.1 License Grant to Jazz. Subject to the terms and conditions of this Agreement, Werewolf hereby grants to Jazz:

(a) an exclusive (even as to Werewolf and its Affiliates), transferable, sublicensable (through multiple tiers and in accordance with Section 3.2), worldwide license, under the Licensed Patents, solely to Exploit Licensed Compounds and Licensed Products; and

(b) a non-exclusive, transferable, sublicensable (through multiple tiers and in accordance with Section 3.2), worldwide license, under the Licensed Know-How, solely to Exploit Licensed Compounds and Licensed Products.

3.2 Sublicensing. Jazz shall have the right to grant written sublicenses under the licenses granted in Section 3.1 through multiple tiers of sublicenses; provided that each sublicense granted by Jazz pursuant to this Section 3.2 will be subject and subordinate to the terms and conditions of this Agreement. Jazz shall promptly provide [**]. Werewolf shall use commercially reasonable efforts for a period beginning [**] after the Effective Date and ending on the [**] anniversary of the Effective Date, to obtain, from [**]. Werewolf shall promptly notify Jazz upon receiving any such [**] and Jazz's obligations pursuant to this Section 3.2 to provide [**] shall terminate to the extent that [**].

3.3 Subcontracting by Jazz. Jazz shall have the right to use the services of any Third Parties, including distributors, Third Party contract research organizations, or service providers, to perform its Development, manufacturing, and Commercialization activities; provided that Jazz shall remain responsible for such Third Parties' performance on behalf of Jazz under this Agreement.

3.4 License Grant to Werewolf.

(a) Jazz hereby grants to Werewolf, a non-exclusive license, with the right to grant sublicenses to Affiliates and subcontractors, under the Licensed Patents and Jazz Background Patents, solely for the limited purpose of conducting the activities assigned to Werewolf under a Development Plan or as otherwise permitted under Section 5.1 and the exception in Section 4.1.

(b) Jazz hereby grants to Werewolf a paid up, non-exclusive license, with the right to grant sublicenses to Affiliates, subcontractors and Werewolf sublicensees, under [**] that is (i) [**], and (ii) [**], solely to the extent [**] but excluding [**].

3.5 No Implied License; Retained Rights. No right or license under any Intellectual Property Rights is granted or will be granted by either Party by implication. All rights or licenses are or will be granted only as expressly provided in this Agreement. Notwithstanding the non-exclusive nature of the license set forth in Section 3.1(b), Werewolf and its Affiliates shall not use or practice the Licensed Know-How to, or grant any licenses or other rights under the Licensed Know-How to, Exploit Licensed Compounds or Licensed Products without the prior written consent of Jazz, except for the sole purpose of conducting the activities assigned to Werewolf under a Development Plan.

3.6 Confirmatory Patent License. Werewolf shall, if requested to do so by Jazz and at Jazz's reasonable expense, promptly enter into confirmatory license agreements in the form or substantially the form reasonably requested by Jazz for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as Jazz considers appropriate.

3.7 Third Party Agreements. Except with respect to (a) any Third Party payment that is included in a Licensed Product Improvement Fee for a New Domain for which Jazz obtained a license pursuant to Section 5.1(c)(ii) and (b) any New Third Party IP Payments owed to the applicable Third Party licensor for any New Third Party IP for which Jazz took a sublicense pursuant to Section 5.1(c)(ii), Werewolf shall be responsible for all payments owed to its Third Party licensors, including with respect to any rights Werewolf has in and to the Licensed Technology and any payments arising under any Werewolf In-License.

3.8 Licensed Know-How.

(a) Initial Transfer. Promptly following the Effective Date and in any event no later than [**] thereafter, Werewolf shall, and shall use diligent efforts to cause its Affiliates and any contractors to, initiate transfer to Jazz all Licensed Know-How existing as of such date and shall continue to exercise diligent efforts to complete such transfer of Licensed Know-How to Jazz as soon as thereafter reasonably practicable.

(b) Ongoing Transfer. From time to time during the Term and in any event no less frequently than [**], Werewolf shall, and shall use diligent efforts to cause its Affiliates and any contractors, to promptly transfer to Jazz all Licensed Know-How that has not previously been provided to Jazz hereunder, provided that, any manufacturing technology transfer will occur in accordance with Section 8.7. Simultaneously with the submission of any IND Data Package to Jazz in accordance with Section 6.4(a), Werewolf shall provide to Jazz a written report setting out all Licensed Know-How existing at such date.

(c) Cooperation. The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the Licensed Know-How in accordance with this Section 3.8. Without limiting the foregoing, Werewolf shall provide all such items in electronic form to the extent the same exists in electronic form and shall provide copies and an opportunity to inspect (and copy) original versions for all other materials comprising such Licensed Know-How (including for example, original patient report forms and other original source data). It is understood all Licensed Know-How shall be made available to Jazz in the language in which it was created together with all existing translations and summaries thereof. Upon request by Jazz, Werewolf shall, and shall use diligent efforts to cause its Affiliates and any contractors to, reasonably cooperate with and assist Jazz as may be necessary or desirable in order to allow Jazz to understand the Licensed Know-How and to utilize the Licensed Know-How for the purposes contemplated in this Agreement and Werewolf shall promptly provide responses to Jazz's inquiries for clarification or further information relating thereto.

4. Exclusivity.

4.1 During the Term, except for the [**], Werewolf shall not, and shall ensure that its Affiliates shall not, whether on their own or with or through any Third Party (including through licensing to or from any Third Party), [**].

4.2 Subject to Section 19.1, from the Effective Date until the earlier of (a) the [**] anniversary of the Effective Date, or (b) [**], shall not, and shall ensure that its Affiliates shall not, whether on their own or with or through any Third Party (including through licensing to or from any Third Party), [**] (an "**Equivalent Product**").

5. Licensed Compound Creation

5.1

(a) If at any time during the Term, Werewolf or its Affiliates identify, develop, synthesize, create, discover, generate or invent any isolated recombinant polypeptide that falls within the criteria set out in Section 1.79(b), Werewolf shall promptly notify Jazz of all relevant results, data and other details pertaining to such polypeptide and shall promptly and fully respond to any queries or requests for further information that Jazz may make, and such isolated recombinant polypeptide shall automatically be included as a Licensed Compound from the date such isolated recombinant polypeptide was first identified, developed, created, generated or discovered.

(b) If at any time during the Term, Werewolf or its Affiliates identify, develop, synthesize, create, discover, generate or invent any [**] domain or domain described in Section 1.79(b)(i)-(iii) (each such [**] domain or other domain, a "**New Domain**"), then at the next JSC meeting after [**], Werewolf shall disclose to the JSC the [**], including a summary of all relevant results, data and other details related to the New Domain and any Licensed Product Improvement Test Data generated by or on behalf of Werewolf or its Affiliates in their discretion with respect to such New Domain, and Werewolf shall promptly and fully respond to any queries or reasonable requests for further information that Jazz may make. If no Licensed Product Improvement Test Data were included in Werewolf's disclosure to the JSC with respect to a particular New Domain or if the Licensed Product Improvement Test Data so included were insufficient to [**], then Jazz shall have the right, in its discretion and upon notice to Werewolf, to request Werewolf to generate Licensed Product Improvement Test Data for such New Domain [**], in which case Werewolf shall promptly accept or decline such request in writing. If Werewolf accepts such request, it will use diligent efforts to promptly generate and disclose to Jazz such Licensed Product Improvement Test Data. If Werewolf declines Jazz's request to generate the Licensed Product Improvement Test Data for such New Domain, Jazz may generate such Licensed Product Improvement Test Data for such New Domain at Jazz's sole expense and (A) Werewolf shall provide Jazz with all Know-How Controlled by Werewolf or its Affiliates that is necessary or would have been used by Werewolf to facilitate such generation and (B) Jazz will disclose such Licensed Product Improvement Test Data to Werewolf promptly after its generation. [**]. In the event that Werewolf or its Affiliates [**], Jazz shall upon request from Werewolf [**], provided however, pursuant to section [**], Jazz or its Affiliates shall have the right to [**].

(c) If either Party reasonably believes based on the Licensed Product Improvement Test Data for a particular New Domain that such New Domain could [**], then such Party shall provide notice to the other Party of such belief and if the identification, development, synthesis, creation, discovery, generation or invention of such New Domain first occurred:

(i) on or before the [**] anniversary of the Effective Date, such New Domain shall be deemed to automatically have been licensed to Jazz, for use in Licensed Compounds, from the date such New Domain was first identified, developed, created, generated or discovered; or

(ii) after the [**] anniversary of the Effective Date, such New Domain shall be licensed to Jazz for use in Licensed Compounds in accordance with this Section 5.1(c)(ii). If Jazz notifies Werewolf of its interest in potentially obtaining a license to such New Domains, Werewolf shall promptly (1) provide an accounting of its costs (including any payments made or owed to Third Parties) for the identification, development, synthesis, creation, discovery, generation or invention of such New Domain, which costs shall include [**] and shall be pro-rated if (A) [**] or (B) [**] (such costs, the "**Licensed Product Improvement Fee**") and (2) (A) identify in writing any Patents or Know-How that (x) were in-licensed by Werewolf or its Affiliates from a Third Party and not already included in the Werewolf Background IP, (y) are Controlled by Werewolf or its Affiliates, and (z) would be necessary or reasonably useful to Exploit such New Domain as part of a Licensed Compound (such Patents and Know-How, "**New Third Party IP**"), (B) provide Jazz with a copy of the license agreement between Werewolf or its Affiliate and such Third Party with respect to such New Third Party IP, (C) provide detailed written itemization of all milestones, royalties and other payments that would be owed to such Third Party on account of the Exploitation of such New Domain as part of a Licensed Compound if Jazz were to take a sublicense to such New Third Party IP, which milestones and other payments shall be pro-rated [**] (such itemized milestones, royalties and other payments so summarized, the "**New Third Party IP Payments**"). Werewolf shall promptly and fully respond to any queries or requests for further information that Jazz may make. If Jazz decides to take a license for such New Domain, it shall deliver a license exercise notice to Werewolf within [**] of its receipt of all information that Werewolf is obligated to provide pursuant to this Section 5.1(c)(ii), which exercise notice shall identify any New Third Party IP that Jazz wishes to obtain a sublicense to in connection therewith. For each license exercise notice delivered by Jazz pursuant to this Section 5.1(c)(ii), Jazz shall make a payment to Werewolf within [**] of receipt of an applicable invoice issued by Werewolf following such notice for the applicable Licensed Product Improvement Fee, the New Domain shall be licensed to Jazz as of the date of payment of the Licensed Product Improvement Fee and the New Third Party IP identified in Jazz's license exercise notice shall be sublicensed to Jazz (and thereby deemed to be included in the Licensed Technology) as of such date. Thereafter, Jazz shall be solely responsible for any New Third Party IP Payments due to the applicable Third-Party licensor if such New Domain is used by Jazz or its Affiliates or Sublicensees in a Licensed Product and Jazz took a sublicense to the applicable New Third Party IP.

5.2 In the event that any isolated recombinant polypeptide becomes a Licensed Compound pursuant to Section 5.1(a) or any New Domain becomes licensed to Jazz pursuant to Section 5.1(c), Werewolf will:

(a) promptly transfer to Jazz all results and data relating to the applicable isolated recombinant polypeptide or domain, at Jazz's costs and expense; and

(b) cease all work on such isolated recombinant polypeptide or on such domain in conjunction with the other domains described in Section 1.79(b)(i)-(iii), unless otherwise agreed by the Parties in writing.

5.3 Jazz and its Affiliates have the right to identify, develop, synthesize, create, discover, generate and invent Jazz Polypeptides (all of which are Licensed Compounds) and to engage Third Parties to do so, provided that Jazz does not, without Werewolf's prior written consent, [**] (as opposed to prior art) in a published Patent that is owned or controlled by Werewolf and listed on **Schedule 5.3**, which schedule may be updated from time to time by Werewolf upon written notice to Jazz.

6. Development

6.1 Overview. Subject to the terms and conditions of this Agreement, Werewolf shall be responsible for performing IND-Enabling Studies with respect to the Initial Lead Molecule, generating and delivering to Jazz all data and materials necessary for the preparation of an IND for the Initial Lead Molecule, and conducting any other Development activities for Licensed Compounds as the Parties may agree and as are specified in any Development Plan (the "**Werewolf Development Activities**"). Werewolf shall also provide Jazz, at Jazz's reasonable request and expense, with reasonable support with respect to Jazz's preparation of such IND. Jazz shall be responsible, at its sole cost and expense, for all Development activities to Exploit Licensed Products (other than the Werewolf Development Activities), including preparing, filing and owning all applications for Regulatory Approval and handling all interactions with Regulatory Authorities (the "**Jazz Development Activities**").

6.2 Development Plans.

(a) General. The Parties have agreed the Initial Development Plan as of the Effective Date with respect to the pre-clinical Development activities to be conducted by Werewolf on the Initial Lead Molecule. The Parties may, upon mutual agreement, enter into an additional Development Plan, if any, with respect to each of up to [**] Licensed Compounds other than the Initial Lead Molecule. Each Development Plan shall set forth the timeline and details for all Werewolf Development Activities to be conducted pursuant to such plan and shall include a reasonably detailed budget of the costs and expenses for the activities to be conducted pursuant to such plan (such budget the "**Development Budget**"). In addition, the Development Plan shall identify specified personnel of Werewolf to perform and/or oversee the conduct of specific Werewolf Development Activities, including Key Personnel, if applicable. If the terms of the Development Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

(b) Revisions. The JSC shall review each Development Plan (and associated Development Budget) [**] for potential amendment in accordance with this Section 6.2(b). In addition, from time to time, either Party may prepare updates and amendments, as appropriate, to a Development Plan to add, remove or modify the Werewolf Development Activities under such Development Plan ("**Plan Revisions**"). The Party wishing to make such a revision shall submit

a copy of the proposed Plan Revisions to the other Party, via the Working Group, for review and comment. The Working Group shall propose all Plan Revisions to the JSC for review, discussion, and approval.

6.3 Development Costs.

(a) Werewolf shall directly pay all costs for all Werewolf Development Activities. Jazz shall reimburse Werewolf for one hundred percent (100%) of the Werewolf Reimbursable Costs in accordance with Section 6.3(c) or 6.3(d).

(b) Development Budget. The Parties shall meet, on a [**] basis, to discuss and review, line-by-line, the actual costs incurred by Werewolf in performing a Werewolf Development Activities compared to the amounts set forth in the then-current applicable Development Budget with respect thereto.

(c) Pre-Effective Date Werewolf Reimbursable Costs. Werewolf shall submit to Jazz on or no more than [**] before the Effective Date a good faith estimate of the Werewolf Reimbursable Costs incurred, and still to be incurred, by Werewolf between [**] and the Effective Date (the "**Pre-Effective Date Period**"). Within [**] after the Effective Date, Werewolf shall submit to Jazz (i) an invoice setting forth the total Werewolf Reimbursable Costs incurred by Werewolf during the Pre-Effective Date Period, (ii) timesheets indicating the percentage of time and the hour equivalent of such percentage Werewolf personnel allocated to the Development of the Initial Lead Molecule during the Pre-Effective Date Period, as reasonably necessary to confirm the manner and circumstances in which such costs were incurred, and (iii) documentation confirming any out-of-pocket expenses paid by Werewolf for Development of the Initial Lead Molecule during the Pre-Effective Date Period. Such invoice, timesheets and out-of-pocket expenses shall reflect the estimate provided by Werewolf to Jazz on or before the Effective Date, unless otherwise agreed by the Parties. Jazz shall pay the undisputed amount invoiced within [**] after receipt of the invoice. For clarity, FTE Costs of Werewolf's Affiliates shall be treated as FTE Costs of Werewolf and not an out-of-pocket expense. Jazz shall have no responsibility for, nor any liability in respect of, any costs incurred by Werewolf prior to the Effective Date for Development of the Initial Lead Molecule that are not Werewolf Reimbursable Costs.

(d) Estimates and Invoices. At least [**] prior to end of each [**] during the Term, Werewolf shall submit to Jazz in writing a good faith estimate of the total Werewolf Reimbursable Costs incurred by Werewolf in accordance with the Development Budget in such [**]. Such estimate shall be used by Jazz for accounting purposes only and shall not be considered binding on either Party. Within [**] after the end of each month in which Werewolf incurs any Werewolf Reimbursable Costs, Werewolf shall submit to Jazz (i) an invoice setting forth the total Werewolf Reimbursable Costs incurred by Werewolf in accordance with the Development Budget in such month, (ii) monthly timesheets indicating the percentage of time and the hour equivalent of such percentage Werewolf personnel allocated to the Werewolf Development Activities during such month, as reasonably necessary to confirm the manner and circumstances in which such costs were incurred, and (iii) documentation confirming any out-of-pocket expenses paid by Werewolf for Werewolf Development Activities during such month. Any third-party costs that are Werewolf Reimbursable Costs will be invoiced to Jazz within [**] after the end of the month in which the third party invoice is received. Jazz shall pay the

undisputed amounts invoiced within [**] after receipt of the invoice. For clarity, FTE Costs of Werewolf's Affiliates shall be treated as FTE Costs of Werewolf and not an out-of-pocket expense. Jazz shall have no responsibility for, nor any liability in respect of, any costs incurred by Werewolf for the performance of Werewolf Development Activities that are not Werewolf Reimbursable Costs.

6.4 Werewolf Development Activities. Werewolf shall perform the Werewolf Development Activities in accordance with all Applicable Laws, the applicable, then-current Development Plan, and the terms of this Agreement. Werewolf shall (a) generate the data and deliverables specified in the Development Plan using at least the resources specified therein (e.g., FTEs, Key Personnel, and other dedicated resources) and (b) use diligent efforts to complete performance of the Werewolf Development Activities in accordance with the timelines set forth in the Development Plan.

(a) Information and Data Exchange. Werewolf shall keep Jazz fully informed of any progress and results of the Werewolf Development Activities and shall provide any updates and additional information as Jazz may request from time to time. In addition, Werewolf shall provide a written report, including all data and information generated in the performance of the Werewolf Development Activities, to Jazz in a form reasonably acceptable to Jazz on the [**] of each [**] during the period when activities are being performed under any Development Plan. Promptly following completion of any IND-Enabling Studies within the Werewolf Development Activities, Werewolf shall submit to Jazz all data and other information set forth in the applicable Development Plan for inclusion in an IND for the applicable Licensed Compound (the "**IND Data Package**"). Werewolf shall promptly provide to Jazz any data or information that Jazz identifies as missing from such IND Data Package and shall promptly provide responses to Jazz's inquiries for clarification regarding the data and information included in such IND Data Package.

(b) Step-In Rights. Notwithstanding the foregoing, Jazz shall have the right to assume responsibility for carrying out any portion of any Development Plan: (i) If the JSC determines, upon consideration of all circumstances, that Werewolf has made insufficient progress against the Development Plan resulting in a material delay in submission of an IND, (ii) upon an Insolvency Event of Werewolf, or (iii) if Werewolf materially breaches any representation, warranty, covenant, or agreement made by Werewolf in this Agreement that is not cured within [**] of Jazz's written notice thereof. For clarity, Jazz's step-in right under this Section 6.4(b) shall be in addition to, and not in lieu of, any other remedies available to Jazz with respect to Werewolf's material breach. Promptly following Jazz's assumption of responsibility for the performance of Werewolf Development Activities pursuant to this Section 6.4(b), Werewolf shall perform a full technology transfer to Jazz in accordance with Section 3.8.

6.5 Key Personnel. The Parties shall identify in each Development Plan any key Werewolf personnel who will perform or oversee the Werewolf Development Activities (the "**Key Personnel**"). Each Key Personnel shall each devote the percentage of their respective FTE specified in such Development Plan to performing the Werewolf Development Activities, with such FTE allocated in accordance with the timings by [**] in such Development Plan. The performance of Werewolf Development Activities by the Key Personnel (and other Werewolf personnel staffed to perform Werewolf Development Activities) shall receive at least the same level of priority as Werewolf's internal programs.

6.6 Subcontracting by Werewolf. Werewolf shall have the right to subcontract Werewolf Development Activities to Third Parties and Affiliates to the extent that the Werewolf Development Activity to be subcontracted is specifically identified in the applicable Development Plan as being eligible for subcontracting and the subcontractor is identified in the applicable Development Plan as an approved subcontractor; provided that, with respect to each subcontract with a non-Affiliate subcontractor to be entered into after the Effective Date, each subcontractor agrees in writing: (a) to perform the subcontracted Werewolf Development Activities in the same manner that Werewolf is obligated to perform them under this Agreement, (b) to be subject to confidentiality provisions materially similar to the provisions of Article 14, (c) to grant to Werewolf a worldwide, perpetual, irrevocable, royalty-free, fully paid up license (sublicensable through multiple tiers), under its Subcontractor Background IP, to research, develop, manufacture, commercialize and otherwise Exploit the Licensed Products and Licensed Compounds, (d) that, Werewolf solely owns all Intellectual Property Rights generated by such subcontractor in the course of performing the subcontracted Werewolf Development Activities (and can assign such Intellectual Property Rights to Jazz as needed to effectuate the provisions of Section 13.2), provided that, with respect to any such Intellectual Property Rights that (i) [**], (ii) [**], and (iii) [**] ("**Subcontractor Improvement IP**"), Werewolf may, instead of obtaining sole ownership, obtain a worldwide, perpetual, irrevocable, royalty-free, fully paid up license (including a right to sublicense through multiple tiers), under such Subcontractor Improvement IP, to research, develop, manufacture, commercialize and otherwise Exploit the Licensed Products and Licensed Compounds, (e) that Jazz is a Third Party beneficiary of the agreement with such subcontractor, and (f) that such subcontracting agreement will be assigned to Jazz upon Jazz's written request. If, despite Werewolf using commercially reasonable efforts to procure in negotiations a subcontractor's agreement to such terms ((a) through (f)), the subcontractor in question does not agree to such terms, Werewolf shall notify Jazz, and Jazz, in its sole discretion, shall determine whether Werewolf shall enter into a subcontract agreement with such subcontractor. At Jazz's written request, Werewolf will use commercially reasonable efforts to obtain an amendment of its agreement with any Third Party subcontractor that was entered into before the Effective Date to include any of the terms (a) through (f) above that were not already included in such agreement; provided that such efforts shall not require Werewolf to make any payment to such subcontractor for such amendment or seek to obtain a given amendment more than [**] (but Werewolf may attempt to do so at its sole discretion). Additionally, prior to Werewolf engaging an Affiliate subcontractor to conduct Werewolf Development Activities, Werewolf shall have a written agreement in place with such Affiliate that requires (1) the subcontractor to perform the subcontracted Werewolf Development Activities in the same manner that Werewolf is obligated to perform them under this Agreement, (2) the subcontractor to be subject to confidentiality provisions materially similar to the provisions of Article 14, and (3) Werewolf to solely own all Intellectual Property Rights generated by such subcontractor in the course of performing the subcontracted Werewolf Development Activities (with the right to assign such Intellectual Property Rights to Jazz as needed to effectuate the provisions of Section 13.2). For the avoidance of doubt, Werewolf shall remain responsible for all subcontracted work and for all payments and other liabilities owed to its subcontractors.

6.7 Regulatory Inspections. Werewolf shall promptly notify Jazz of any regulatory inspections relating to the performance of a Development Plan by a duly authorized representative ("**Inspector**") of any Regulatory Authority. Werewolf shall provide Jazz with the following data as soon as practicable: (a) the stated purpose of the inspection, (b) the scope of the

inspection and any bearing on Licensed Compounds or Licensed Products, (c) the name and credential number of the Inspector, and (d) a copy of the form(s) issued by the Inspector, if any. To the extent permitted by Applicable Laws, Werewolf shall permit Jazz to attend any inspections relating to the Werewolf Development Activities. Unless otherwise required by Applicable Laws, Werewolf shall not provide any copies of any Development Plan or other Confidential Information of Jazz to the Inspector and if permitted by Applicable Laws shall forward any requests for such materials by an Inspector to Jazz. Jazz shall have the primary responsibility for preparing any responses to the extent they relate to any Licensed Compound or Licensed Product (but not any other matter) that may be required by the Regulatory Authority, and Werewolf shall have the primary responsibility for preparing any responses relating to the method of performing the Werewolf Development Activities and Werewolf's operations and procedures; provided, however, that Werewolf shall provide any proposed material correspondence with a Regulatory Authority related to the Werewolf Development Activities to Jazz for review and comment at least [**] before submission (or [**] before submission, if the Regulatory Authority requires a response in less than [**]). Jazz shall provide any such comments in writing within [**] of receipt of such correspondence (or such shorter period if required by the circumstances) and Werewolf shall incorporate any reasonable comments received from Jazz during such period. Nothing in this Section 6.7 shall require Werewolf to breach Applicable Laws.

6.8 Development Records.

(a) Each Party shall, itself or through its Affiliates, create and maintain records (in a format consistent with the Party's customary record-keeping practices and reasonably acceptable to the other Party) of the data and other information generated or recorded in the performance of the Werewolf Development Activities or Jazz Development Activities, as the case may be, ("**Development Records**") in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which Development Records shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of any Werewolf Development Activities or Jazz Development Activities. Each Party shall or shall procure that its Affiliates shall (as applicable) retain the Development Records for at least [**] after the expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law.

(b) All Development Records in the possession of Werewolf or its Affiliates shall be maintained and managed (i) separately from files generated, managed, or maintained by Werewolf for its other programs, (ii) in a manner so they can be quickly and accurately produced when required by Jazz pursuant to the provisions of this Agreement, and (iii) in compliance with Applicable Laws.

(c) All Development Records in the possession of Jazz or its Affiliates shall be maintained and managed (i) separately from files generated, managed, or maintained by Jazz for its other programs, (ii) in a manner so they can be quickly and accurately produced when required by Werewolf pursuant to the applicable provisions of Section 17.7 in the event of termination of this Agreement by Jazz pursuant to Section 17.2or by Werewolf pursuant to Section 17.3, and (iii) in compliance with Applicable Laws.

(d) Upon Jazz's written request and expense, and with at least [**] prior notice, Werewolf shall permit Jazz's employees (subject to execution of a written confidentiality agreement on customary terms and its agreement to comply with Werewolf's on-site policies) to visit Werewolf's or its Affiliates' facilities during normal business hours to review the Development Records, inspect those facilities of Werewolf or its Affiliates which are being utilized in the performance of the Werewolf Development Activities, and make copies of relevant Development Records. Jazz shall be entitled to have performed such inspection of Development Records and Werewolf's or its Affiliates' facilities no more than [**] period (except for cause) during the Term and no more than [**] Jazz employees shall be permitted on the Werewolf premises at a time to conduct such inspection.

(e) With respect to any Development Records for which copies have not been provided to Jazz, Werewolf shall, prior to the deletion or destruction of any such Development Records, notify Jazz. Following any such notification Jazz shall have [**] to request Werewolf in writing either to (i) provide a copy of such Development Records to Jazz and/or (ii) delete or destroy such Development Records. If Jazz does not provide notification to Werewolf within such [**] period then, for clarity, Werewolf shall be free to delete/destroy such Development Records.

6.9 Personnel and Resources. Werewolf shall maintain adequate personnel and resources to meet its obligations under this Agreement. Werewolf shall pay any and all salary, wages or other compensation to, and make any contributions for taxes, unemployment insurance, social security and other benefits for, its employees, agents and consultants performing under this Agreement.

6.10 Employment and Labor Matters. Nothing in this Agreement is intended to transfer the employment of employees engaged in the provision of any Werewolf Development Activities from Werewolf to Jazz. All Representatives of Werewolf and any of its Affiliates will be deemed for all compensation, employee benefits, tax and social security contribution purposes to be employees or representatives of Werewolf or its Affiliates (or their subcontractors) and not employees or representatives of Jazz or any of its Affiliates. In providing the Werewolf Development Activities, such employees and representatives of Werewolf and its Affiliates (or their subcontractors) will be under the direction, control and supervision of Werewolf or its Affiliates (or their subcontractors) and not of Jazz or its Affiliates.

6.11 Jazz Development Plan.

(a) Prior to [**], Jazz will prepare and submit to the JSC for discussion a written high-level plan setting forth the key Development activities contemplated to be performed by Jazz through [**], and including [**] for such activities. Jazz shall discuss the Jazz Development Plan at the next JSC meeting after such submission [**].

(b) Jazz shall present to the JSC for discussion each proposed [**] update to the Jazz Development Plan before it is finalized and shall notify the JSC if it makes changes to the Jazz Development Plan between such [**] updates.

(c) Jazz shall perform the Jazz Development Activities in accordance with all Applicable Laws and the applicable terms of this Agreement.

6.12 Jazz Diligence.

(a) Commencing upon [**], Jazz shall use Commercially Reasonable Efforts to (i) [**] and (ii) [**]. Jazz shall have the right to satisfy its diligence obligation under this Section 6.12 through its Affiliates and Sublicensees.

7. Regulatory

7.1 General. Jazz, or its Affiliates or Sublicensees, will be responsible for all regulatory activity associated with the Exploitation of Licensed Compounds or Licensed Products and shall own and control any and all Regulatory Approvals and any and all other regulatory communications and regulatory filings received and submitted in connection with seeking and maintaining Regulatory Approvals for the Licensed Products. Werewolf shall provide to Jazz all reasonable assistance requested by Jazz in connection therewith, including providing any documentation or other materials Controlled by Werewolf or its Affiliates as may be necessary or useful for Jazz or any of its Affiliates or its or their Sublicensees to prepare, file, obtain and maintain Regulatory Approvals for Licensed Products and to respond to regulatory communications. Except to the extent prohibited by Applicable Law, all regulatory documentation (including all Regulatory Approvals) relating to any Licensed Product shall be owned by and shall be held in the name of Jazz or its designated Affiliate, Sublicensee or designee.

8. Manufacturing

8.1 Process Development. At Jazz's request and expense prior to completion of the manufacturing technology transfer pursuant to Section 8.7, Werewolf shall use commercially reasonable efforts to develop processes and expertise required to manufacture the Initial Lead Molecule, and, to the extent mutually agreed by the Parties, one or more other Licensed Compounds, for clinical purposes.

8.2 Supply.

(a) Subject to Section 8.7, below, and in accordance with the terms and conditions set forth in any Development Plan, including timelines therein, Werewolf shall manufacture (or have manufactured) and supply (or have supplied), a sufficient quantity of Licensed Product for Werewolf to perform all Werewolf Development Activities. Jazz shall reimburse Werewolf for its costs to supply such Licensed Product as specified in the applicable Development Budget.

(b) The Parties have agreed to the requirements for Licensed Product for use in the Phase 1 Clinical Trial for the Initial Lead Molecule as provided in **Schedule 8.2(b)**. Werewolf will initiate the order with the Third Party manufacturer within [**] of the Effective Date, shall supply to Jazz [**], in consideration for Jazz paying such agreed Cost of Goods for such Licensed Product in accordance with the terms of this Article 8, and shall use diligent efforts to ensure that [**]. Werewolf will use diligent efforts to [**].

(c) In addition, at Jazz's written request, Werewolf will supply Jazz with the Initial Lead Molecule or Licensed Product containing the Initial Lead Molecule, or, to the extent

mutually agreed by the Parties, one or more other Licensed Compounds or Licensed Products for clinical purposes, provided that:

(i) such supply by Werewolf of such Licensed Product is [**],

(ii) Jazz is [**],

(iii) Werewolf is [**], and

(iv) Jazz shall reimburse Werewolf for its costs of supplying such Licensed Compound or Licensed Product at Werewolf's Cost of Goods.

8.3 Quality. Promptly after the Effective Date, the Parties shall negotiate in good faith and enter into a quality agreement, which will provide for customary and commercially reasonable terms and conditions relating to the quality requirements for the manufacture and supply of Licensed Compounds and Licensed Products by or on behalf of Werewolf. Werewolf will maintain and follow a quality control testing and quality assurance program consistent with the applicable specifications, good manufacturing practices, and all other requirements of Applicable Law and consistent with industry standards.

8.4 Ordering. Jazz may, from time to time, submit a written purchase order to Werewolf for the clinical supply of Licensed Compound or Licensed Product pursuant to the provisions of Section 8.2(c). Any such purchase order shall be confirmed by Werewolf within [**] of receipt, [**]. Werewolf will use its commercially reasonable efforts to [**] under this Agreement. Once a purchase order is agreed, it shall be binding on both Parties. For the avoidance of doubt, no purchase orders are required to be submitted in respect of any supply in accordance with Section 8.2(b).

8.5 Delivery. All Licensed Compound and Licensed Product supplied under this Agreement shall be manufactured and supplied in accordance with the Quality Agreement and, with the exception of the Licensed Product used by Werewolf in the Werewolf Development Activities pursuant to Section 8.2(a), shall be delivered to Jazz *FCA* (Incoterms 2020) from Werewolf's designated Third Party contract manufacturer's facility in the United States. Title and risk of loss and damage to any such Licensed Compound or Licensed Product purchased under this Agreement shall pass to Jazz on delivery.

8.6 Information; Updates. Werewolf shall promptly disclose to Jazz in writing the details of any failure, defect or other issue concerning the supply of Licensed Compound or Licensed Products under this Agreement, including any failure to fully comply with cGMP or the requirements of the Quality Agreement, to produce Licensed Product fully meeting all specifications, or any delay of any delivery of Licensed Product. Werewolf will share the results of any consequent investigations, including any investigation into the performance of any Third Party with Jazz, and the Parties shall discuss in good faith how to prevent such issues arising in the future.

8.7 Manufacturing Technology Transfer. Within [**] after its receipt of the written request of Jazz [**] manufactured as provided in Section 8.2(b), above, Werewolf shall, at [**] cost and expense, commence the performance of a manufacturing technology transfer to

Jazz, its nominated Affiliate or a Third Party contract manufacturer designated by Jazz of all Licensed Know-How which is necessary or useful to manufacture or have manufactured Licensed Compounds and Licensed Product. Such manufacturing technology transfer shall be performed pursuant to a mutually agreed manufacturing technology transfer plan, which sets out the activities, timelines and budget for such technology transfer (the "**Technology Transfer Plan**"). Jazz shall prepare a draft Technology Transfer Plan and provide it to Werewolf for Werewolf's review and comment. Jazz shall incorporate Werewolf's reasonable comments into the draft Technology Transfer Plan to generate the final Technology Transfer Plan. As part of such Technology Transfer Plan, the Parties shall agree on terms relating to, amongst others: (i) [**], (ii) [**], (iii) [**], (iv) [**], and (v) [**]. Each Party shall perform the activities allocated to it under the Technology Transfer Plan in accordance with the timelines set forth therein, provided that the Parties shall adjust such timelines in the Technology Transfer Plan as reasonably necessary due to technical issues. Following completion of the manufacturing technology transfer, as between the Parties and except for any ongoing supply pursuant to Section 8.2, Jazz shall have the exclusive right to conduct or have conducted, and be solely responsible for, at its sole cost and expense, the manufacture and supply of all Licensed Compounds and Licensed Products. Werewolf shall provide all such technical assistance and support to Jazz as Jazz may require in order to manufacture or have manufactured Licensed Compounds or Licensed Products.

9. Commercialization

9.1 Commercialization. As between the Parties, Jazz shall have the exclusive right to conduct and be solely responsible, at its sole cost and expense, for the Commercialization of all Licensed Compounds and Licensed Products worldwide, including (a) negotiating with applicable Governmental Bodies regarding the price and reimbursement status of Licensed Compounds and Licensed Products, (b) marketing and promotion, (c) booking sales and distribution and performance of related services, (d) handling all aspects of order processing, invoicing and collection, inventory and receivables, (e) providing customer support, including handling medical queries, and performing other related functions, and (f) conforming its practices and procedures to Applicable Laws relating to the marketing, detailing and promotion of Licensed Compounds or Licensed Products.

10. Payments

10.1 Upfront Payment. Jazz shall pay to Werewolf an upfront payment of Fifteen Million Dollars ($15,000,000) within ten (10) Business Days following the Effective Date, in accordance with the payment provisions of Article 11 and subject to receipt by Jazz of the applicable invoice from Werewolf.

10.2 Milestone Payments.

(a) Development Milestone Payments. Jazz shall pay to Werewolf the one-time milestone payments set forth below following the first achievement, by Jazz, and/or any of its Affiliates or Sublicensees, of the corresponding milestone events defined below (each, a "**Development Milestone Payment"** and "**Development Milestone Event,**" respectively):

	Development Milestone Event	Development Milestone Payment
1.	[**]	[**]
2.	[**]	[**]
3.	[**]	[**]
4.	[**]	[**]
	Total Development Milestone Payments for all Licensed Products	**[**]**

(b) Regulatory Milestones. Jazz shall pay to Werewolf the one-time milestone payments set forth below following the first achievement by Jazz, and/or any of its Affiliates or Sublicensees, of the corresponding milestone events defined below (each, a "**Regulatory Milestone Payment"** and "**Regulatory Milestone Event,**" respectively):

	Regulatory Milestone Event	Regulatory Milestone Payment
1.	[**]	[**]
2.	[**]	[**]
3.	[**]	[**]
4.	[**]	[**]
5.	[**]	[**]
6.	[**]	[**]
7.	[**]	[**]
8.	[**]	[**]
	Total Regulatory Milestone Payments for all Licensed Products	**[**]**

(c) First Indication and Second Indication. For the avoidance of doubt, notwithstanding the foregoing, no Development Milestone Event or Regulatory Milestone Event can be achieved (or be deemed achieved) for [**]. Upon the first achievement of Regulatory Milestone Event [**] with respect to a [**] that [**], Jazz shall pay the full amount of the corresponding Regulatory Milestone Payment and no further payments shall be owed with respect thereto. Upon the first achievement of Regulatory Milestone Event [**] with respect to a [**] that [**], if (i) [**], (ii) [**], and (iii) [**], then Jazz shall pay the full amount of the corresponding Regulatory Milestone Payment. Upon the first achievement of Regulatory Milestone Event [**] with respect to a [**] that [**], if (i) [**] and (ii) [**], then Jazz shall make a payment of [**] percent ([**]%) of the corresponding Regulatory Milestone Payment and the remaining [**] percent ([**]%) of the corresponding Regulatory Milestone Payment shall be payable upon the first achievement of such Regulatory Milestone Event with respect to the [**].

(d) Development Milestone 2. Development Milestone 2 will be payable as follows:

(i) [**], Development Milestone Event 2 will be first achieved upon [**] and Development Milestone Payment 2 will become due [**].

(ii) [**].

(iii) In no event will the aggregate amount paid under this Section 10.2(d) exceed $[**].

(e) Skipped Development Milestone. In the event that Development Milestone Event [**] has not yet been achieved at the time of the achievement of Development Milestone Event [**]*, then it* shall be deemed to have been achieved and the Development Milestone Payment for Development Milestone Event [**] shall be due at the same time as the Development Milestone Payment for Development Milestone Event [**]. In the event that Development Milestone Event [**] *or* Development Milestone Event [**] has not yet been achieved at the time of the achievement of Development Milestone Event [**], then such Development Milestone Event shall be deemed to have been achieved and Development Milestone Payment(s) for such Development Milestone Event(s) shall be due at the same time as the Development Milestone Payment for Development Milestone [**]. In the event that Development Milestone Event [**], Development Milestone Event [**] or Development Milestone Event [**] has not yet been achieved at the time of the achievement of Regulatory Milestone Event [**], then such Development Milestone Event shall be deemed to have been achieved and the Development Milestone Payment(s) for such Development Milestone Event(s) shall be due at the same time as the Regulatory Milestone Payment for Regulatory Milestone Event [**].

(f) [**] Trials. In the event that Jazz or any of its Affiliates or Sublicensees [**]. By way of example only, [**].

(g) One-Time Payments. Each of the Development Milestone Payments and Regulatory Milestone Payments set forth in this Section 10.2 shall be paid no more than once with respect to all Licensed Products collectively, and no amounts shall be due hereunder for any subsequent or repeated achievement of any Development Milestone Event or Regulatory Milestone Event by Jazz, its Affiliates or Sublicensees, regardless of the number of Licensed Products with respect to which, or the number of times with respect to any Licensed Product, such Milestone Event occurs. Accordingly, in no event shall the aggregate amount to be paid to Werewolf pursuant to (i) Section 10.2(a) exceed [**] Dollars ($[**]), (ii) Section 10.2(b) exceed [**] Dollars ($[**]) and (iii) Sections 10.2(a) and 10.2(b) combined exceed Five Hundred and Twenty Million Dollars ($520,000,000).

(h) Reports and Payments. Jazz shall notify Werewolf in writing within [**] after the achievement of each Development Milestone Event and Regulatory Milestone Event set out in this Section 10.2 by Jazz, or any of its Affiliates, and in the case of Sublicensees, within [**] after such Development Milestone Event or Regulatory Milestone Event is achieved by such Sublicensee. Based on this notice, Werewolf shall then issue and send to Jazz the invoice for the appropriate Milestone Payment, which shall be paid by Jazz within [**] of receipt of such invoice.

10.3 Sales-Based Milestone Payments.

(a) Sales Milestones. Jazz shall pay to Werewolf the one-time sales milestone payments set out below when Annual Net Sales of all Licensed Products (combined) in the relevant jurisdiction reaches the respective thresholds (each, a "**Sales Milestone Payment**" and a "**Sales Milestone Event,**" respectively), in accordance with this Section 10.3 and the

payment provisions in Article 11 and following receipt of the relevant invoice from Werewolf as further described in Section 10.3(d).

Milestone Event	Milestone Payment
Annual Net Sales of all Licensed Products in the United States first exceed [**] Dollars ($[**])	[**]
Annual Net Sales of all Licensed Products in the United States first exceed [**] Dollars ($[**])	[**]
Annual Net Sales of all Licensed Products in the United States first exceed [**] Dollars ($[**])	[**]
Annual Net Sales of all Licensed Products in the United States first exceed [**] Dollars ($[**])	[**]
Annual Net Sales of all Licensed Products in the United States first exceed [**] Dollars ($[**])	[**]
Annual Net Sales of all Licensed Products in the Rest of the Territory first exceed [**] Dollars ($[**])	[**]
Annual Net Sales of all Licensed Products in the Rest of the Territory first exceed [**] Dollars ($[**])	[**]
Annual Net Sales of all Licensed Products in the Rest of the Territory first exceed [**] Dollars ($[**])	[**]
Annual Net Sales of all Licensed Products in the Rest of the Territory first exceed [**] Dollars ($[**])	[**]
Total Sales Milestone Payments for all Licensed Products	**$740,000,000**

(b) One-Time Payments. Each of the foregoing Sales Milestone Payments shall be paid no more than once and no amounts shall be due hereunder for any subsequent or repeated achievement of any Sales Milestone Event by Jazz, its Affiliates or Sublicensees. In no event shall the aggregate amount to be paid to Werewolf pursuant to this Section 10.3 exceed Seven Hundred and Forty Million Dollars ($740,000,000).

(c) Territory-Based Sales. For the avoidance of doubt, references in Section 10.3 and 10.4 to (i) Annual Net Sales of Licensed Products in the United States shall mean Annual Net Sales of Licensed Products where such sale has, in accordance with the selling party's accounting standards, consistently applied, been booked in the United States; and (ii) Annual Net Sales of Licensed Products in the Rest of the Territory shall mean Annual Net Sales of Licensed Products where such sale has, in accordance with the selling party's accounting standards, consistently applied, been booked in the Rest of the Territory. In no event shall the sale of a single unit of Licensed Product shall be booked in both the United States and the Rest of the Territory.

(d) Notice and Payment. Jazz shall notify Werewolf in writing within [**] after the end of the Calendar Year of the first achievement, by or on behalf of Jazz or its Affiliates or Sublicensees, of each Sales Milestone Event set forth in this Section 10.3. Following receipt of each such notice, Werewolf shall issue to Jazz an invoice for the applicable Milestone Payment. Jazz shall pay to Werewolf the applicable Milestone Payment within [**] after receipt of Werewolf's invoice therefor.

10.4 Royalty Payments.

(a) Base Royalties for Sales of Licensed Products in the United States. Subject to the terms and conditions of this Agreement including the remainder of this Section 10.4, in consideration for the rights and licenses granted under this Agreement, Jazz shall, during the applicable Royalty Term, pay to Werewolf the following running royalties on Annual Net Sales of all Licensed Products (combined) in the United States by Jazz, its Affiliates and their Sublicensees, in accordance with this Section 10.4 and the payment provisions in Article 11, equal to the following percentages of such Annual Net Sales:

Annual Net Sales of all Licensed Product in the United States	**Royalty Rate**
Portion of Annual Net Sales of all Licensed Products in the United States less than [**] Dollars ($[**])	[**]%
Portion of Annual Net Sales of all Licensed Products in the United States greater than or equal to [**] Dollars ($[**]) and less than [**] Dollars ($[**])	[**]%
Portion of Annual Net Sales of all Licensed Products in the United States greater than or equal to [**] Dollars ($[**])	[**]%

(b) Base Royalties for Sales of Licensed Products in the Rest of the Territory. Subject to the terms and conditions of this Agreement including the remainder of this Section 10.4, in consideration for the rights and licenses granted under this Agreement, Jazz shall, during the applicable Royalty Term, pay to Werewolf the following running royalties on

Annual Net Sales of all Licensed Products (combined) in the Rest of the Territory by Jazz, its Affiliates and their Sublicensees, in accordance with this Section 10.4 and the payment provisions in Article 11, equal to the following percentages of such Annual Net Sales:

Annual Net Sales of all Licensed Product in the Rest of the Territory	**Royalty Rate**
Portion of Annual Net Sales of all Licensed Products in the Rest of the Territory less than [**] Dollars ($[**])	[**]%
Portion of Annual Net Sales of all Licensed Products in the Rest of the Territory greater than or equal to [**] Dollars ($[**]) and less than [**] Dollars ($[**])	[**]%
Portion of Annual Net Sales of all Licensed Products in the Rest of the Territory greater than or equal to [**] Dollars ($[**])	[**]%

(c) Royalty Term. Royalties shall be paid from the First Commercial Sale of such Licensed Product in a country by or on behalf of Jazz, its Affiliates, or Sublicensees, until the expiration of the Royalty Term for such Licensed Product in such country. After the expiration of the applicable Royalty Term with respect to a Licensed Product in a country, no further royalties shall be due with respect to such Licensed Product in such country and the licenses and rights granted by Werewolf to Jazz under this Agreement with respect to such Licensed Product (and the Licensed Compound(s) included therein) in such country will become fully paid-up, royalty-free, perpetual and irrevocable.

(d) Royalty Adjustments.

(i) Third Party Payments. If Jazz, or any of its Affiliates or Sublicensees become obligated to make payment to a Third Party with respect to Intellectual Property Rights owned or controlled by such Third Party that are [**] ("**Third Party Payments**"), Jazz may deduct [**] percent ([**]%) of the amount payable to each such Third Party from the royalty payable to Werewolf under this Section 10.4.

(ii) Valid Claim Coverage. If the composition of matter of the Licensed Compound contained in a given Licensed Product is not Covered by a Valid Claim of a Licensed Patent in the country in which such Licensed Product is sold, then the royalty payable by Jazz with respect to the sale of such Licensed Product in such country shall be reduced by [**] percent ([**]%) of the amount otherwise payable pursuant to this Section 10.4.

(iii) Generic Version. On a Licensed Product-by-Licensed Product and country-by-country basis, if in a Calendar Quarter one or more Generic Versions of such Licensed Product is sold in such country, the amount payable to Werewolf pursuant to this Section 10.4 for Net Sales of such Licensed Product in such country shall be reduced by [**]

percent ([**]%) for such Calendar Quarter. If such an adjustment is made for [**] Calendar Quarters with respect to such Licensed Product, then such reduction shall continue for the remainder of the applicable Royalty Term for such Licensed Product in such country.

(iv) Royalty Floor. Notwithstanding the royalty adjustments set out in this Section 10.4(d) and Section 13.5 and, if applicable, any reduction in the payments under this Agreement arising from Jazz's exercise of its alternative remedy set out in Section 17.5, in no event will the aggregate amount of royalties due to Werewolf for a Licensed Product in a country in the Territory in any given Calendar Quarter during the Royalty Term for such Licensed Product in such country be reduced by more than [**] percent ([**]%) of the amount that otherwise would have been due and payable to Werewolf in such Calendar Quarter for such Licensed Product in such country under Section 10.4(a) or Section 10.4b), as applicable.

(v) One Royalty. No more than one royalty payment shall be due under this Agreement with respect to a sale of a particular Licensed Product (e.g., even if such Licensed Product is Covered by multiple Valid Claims or multiple Licensed Patents or contains, incorporates or comprises multiple Licensed Compounds).

(e) Royalty Reports. Commencing with the Calendar Quarter in which the First Commercial Sale of a Licensed Product occurs in the Territory, Jazz shall deliver to Werewolf a report (each, a "**Royalty Report**") setting out the following details as reasonably necessary to calculate the payments due under this Section 10.4:

(i) the calculation of Net Sales of the Licensed Products in such Calendar Quarter;

(ii) the royalties, payable in United States Dollars, which shall have accrued under this Agreement based upon such Net Sales of Licensed Products; and

(iii) the exchange rates used in determining the amount of royalties payable in United States Dollars, as more specifically provided in Section 11.1.

Royalty Reports shall be due [**] following the end of each such Calendar Quarter during the term of this Agreement. Promptly following the delivery of the applicable Royalty Report, Werewolf will invoice Jazz for the royalties due to Werewolf under Section 10.4 above with respect to the Net Sales in the Territory in such Calendar Quarter. Jazz will pay such amounts to Werewolf within [**] following Jazz's receipt of such invoice. Notwithstanding Section 1.91 above, if Jazz receives substantial royalties from a Sublicensee based upon Net Sales of Licensed Products by or under authority of such sublicense, at its election, Jazz may substitute the corresponding definition of "net sales" from its agreement with such Sublicensee (as it applies to Licensed Products, *mutatis mutandis*) for the definition of Net Sales in Section 1.91 for purposes of calculating the Annual Net Sales of the Sublicensee under Section 10.4 above, to the extent such Sections are otherwise applicable.

11. PAYMENTS; BOOKS AND RECORDS

11.1 Exchange Rate; Manner and Place of Payment. All invoices issued hereunder shall be, and all payments hereunder shall be payable, in Dollars. With respect to conversion of

any Development cost incurred made in any currency other than Dollars, Werewolf shall convert the amount to Dollars using the monthly average exchange rate between each currency of origin and Dollars as reported by the *Wall Street Journal* (New York edition), or an equivalent resource as agreed by the Parties in writing. With respect to conversion of any Net Sales made in any currency other than Dollars, Jazz shall convert the amount to Dollars using the exchange rate mechanism generally applied by Jazz in preparing its financial statements for the applicable Calendar Quarter; provided, that such mechanism is in compliance with GAAP. All payments owed to Werewolf under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Werewolf, unless otherwise specified in writing by Werewolf.

11.2 Late Payments. In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, without limiting any other right or remedy of Werewolf, Jazz shall pay interest on the overdue sum accrued from the due date until the date of payment of the overdue amount, whether before or after judgment. Interest under this Section 11.2 will accrue each day at [**], or the maximum applicable legal rate, if less, calculated based on the total number of days payment is delinquent.

11.3 Taxes.

(a) It is the understanding of the Parties as of the Effective Date that no value-added, goods and services sales, use or similar taxes, levies or charges, will be imposed by applicable taxing authorities with respect to provision of the Werewolf Development Activities to Jazz or any payment hereunder ("**Service Taxes**").

(b) Notwithstanding anything in this Agreement to the contrary, if an action (including any assignment of this Agreement, any transfer of payment obligations hereunder, or any failure to comply with Applicable Laws or filing or record retention requirements) by Werewolf leads to the imposition of Service Taxes that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then Werewolf shall bear responsibility for such Service Taxes.

(c) Notwithstanding any other provision of this Agreement, Jazz shall be entitled to deduct and withhold from any payments such amounts as it is required to deduct and withhold pursuant to any tax laws of any jurisdiction or any regulation of any taxing authority thereof. To the extent such amounts are deducted, withheld and paid by or on behalf of Jazz to the appropriate taxing authority, such amounts shall be treated for all purposes of this Agreement as having been paid to Werewolf. Jazz shall provide Werewolf with official receipts issued by the appropriate governmental agency to Jazz. Each Party shall provide to the other Party such assistance as may be reasonably requested in connection with any application to qualify for the benefit of a reduced rate of withholding taxation, under the terms of any income tax treaty between Ireland and other jurisdictions.

12. Audits

12.1 Financial Records of Werewolf; Audits by Jazz. Werewolf (on behalf of itself and its Affiliates) shall maintain accurate and complete records and accounts relating to performance of each Werewolf Development Activity, and, in accordance with generally accepted accounting principles, complete and accurate records of all Werewolf Reimbursable Costs incurred, including all supporting evidence, sufficient to document those amounts invoiced to Jazz for at least [**] following the date of the invoice ("**Financial Records**"). Upon Jazz's written request and expense, Werewolf shall permit Jazz or an independent public accountant (subject to execution of a written confidentiality agreement on customary terms) to audit the Financial Records to verify Werewolf's compliance with this Agreement, such audit to occur at Werewolf's place of business during normal business hours and at Jazz's expense except to the extent specified in the last sentence of this Section 12.1. Jazz shall be entitled to perform such audits of Financial Records no more than [**] period (except for cause) during the Term. If Jazz discovers as a result of any such audit that Werewolf overcharged Jazz, Werewolf shall promptly refund to Jazz the amount of any overcharging. In addition, if the amount of any such overcharge exceeds [**] percent ([**]%) of the amounts actually due during the period being audited, Werewolf shall reimburse Jazz for all costs and expenses incurred in such audit.

12.2 Financial Records of Jazz; Audits by Werewolf. Jazz shall keep, and shall require its Affiliates to keep, accurate records pertaining to the sale or other disposition of Licensed Products in sufficient detail to permit Werewolf to determine or confirm the occurrence of any Sales Milestone Event and the accuracy of Net Sales reported, and the applicable Sales Milestone Payments and royalty payments due hereunder. Jazz will keep such books and records for [**] following the Calendar Year to which they pertain, or such longer period of time as may be required by Applicable Laws. Upon reasonable prior notice and during regular business hours at such place or places where such records are customarily kept, Jazz's records may be inspected on Werewolf's behalf by an independent certified public accountant (the "**Auditor**") selected by Werewolf and reasonably acceptable to Jazz for the sole purpose of verifying for Werewolf the accuracy of the financial reports furnished by Jazz pursuant to this Agreement or of any payments made, or required to be made, to Werewolf pursuant to this Agreement. Such audits may not (i) be conducted for any Calendar Year ending more than [**] prior to the date of such request, (ii) be conducted more than [**] or (iii) be repeated for any [**]. Werewolf shall require the Auditor to provide to Jazz an audit report containing its conclusions regarding any audit, and specifying whether the amounts paid were correct or, if incorrect, the amount of any underpayment or overpayment. The Auditor shall provide to Jazz a preliminary copy of its audit report and shall discuss with Jazz any issues or discrepancies that Jazz identifies. If such audit establishes that additional payments are properly owed to Werewolf in accordance with this Agreement during the period covered by any audit pursuant to this Section 12.2, Jazz shall remit to Werewolf within [**] of the date on which Werewolf delivers to Jazz an invoice for such amounts: (i) the amount of such additional milestone payment or royalties; and (ii) interest on such amount which shall be calculated pursuant to Section 11.2. In the event such audit establishes that amounts were overpaid by Jazz during such period, the amount of such overpayment shall promptly be refunded to Jazz. The fees charged by the independent accountant in connection with any audit pursuant to this Section 12.2 shall be paid by Werewolf; provided, however, that if a discrepancy in favor of Werewolf of more than [**] percent ([**]%) of the payments due hereunder for the period being audited is established, then Jazz shall pay the reasonable fees and expenses charged by such Auditor in connection with such audit.

12.3 Confidential Financial Information. Each Party shall treat all financial information of the other Party subject to review under this Article 12 as confidential. The Auditor shall enter into confidentiality terms acceptable to both Parties before any audit under Section 12.2 is conducted. The Auditor shall not disclose the audited Party's Confidential Information to the auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments to or by the audited Party under this Agreement.

13. Intellectual Property

13.1 Patent Working Group. The JSC shall establish a working group to assist in the communication, identification, and filing of Product Patents (the "**Patent Working Group**"), and each Party (through its representatives on the Patent Working Group) shall use diligent efforts to ensure that there are sufficient Product Patents claiming each Licensed Compound and Licensed Product, including by Werewolf filing divisional or continuing applications of Licensed Patents with focused claims that would qualify as Product Patents. If the Patent Working Group determines that is not feasible or advisable to pursue a Product Patent in a given country due to patent prosecution regulations in such country that are more restrictive than those in the United States, then the Patent Working Group shall devise a plan for providing Jazz with patent prosecution, maintenance and enforcement rights that are as close as possible to what it would have had if it were feasible or advisable to pursue a Product Patent. Until such plan is agreed, at Jazz's request, Werewolf shall (a) file one or more claims in a Licensed Patent in such country that solely claim the composition of matter, manufacture or method of use of one or more Licensed Compounds or Licensed Products and (b) permit Jazz to control the prosecution (including amendment), maintenance and enforcement of such claims as if such claims were included in a Product Patent. The Patent Working Group shall also agree upon a strategy to [**], and such strategy to include [**] (a) [**] and (b) [**], including any [**] (i) [**], (ii) [**], (iii) [**], and (iv) [**]. The Patent Working Group shall meet as necessary to perform its responsibilities or as otherwise directed by the JSC and shall continue to exist only for so long as the JSC determines it is reasonably necessary.

13.2 Ownership of Intellectual Property.

(a) United States Law. For purposes of establishing the Parties' respective ownership of intellectual property conceived, discovered, developed, or otherwise made under this Agreement, inventorship of Information and inventions conceived, discovered, developed, or otherwise made under this Agreement shall be determined in accordance with Applicable Law in the United States as such law exists from time to time, irrespective of where such conception, discovery, development or making occurs.

(b) Werewolf Ownership. As between the Parties, Werewolf shall solely own any and all Werewolf Development IP.

(c)Jazz Ownership. As between the Parties, Jazz or an Affiliate designated by Jazz shall solely own any and all Jazz Development IP, and Werewolf hereby assigns all of its right, title and interest in and to any Jazz Development IP to Jazz.

13.3 Maintenance and Prosecution of Patents.

(a) Werewolf Patents. Werewolf shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain worldwide the Licensed Patents that are not Product Patents, at Werewolf's sole cost and expense, using patent counsel approved by Jazz, such approval not to be unreasonably withheld, conditioned or delayed. Werewolf shall ensure that the Werewolf Development Patents do not disclose or claim any Jazz Development Know-How. Werewolf shall keep Jazz fully informed of all steps with regard to the preparation, filing, prosecution, and maintenance of such Licensed Patents and shall perform all such actions in good faith. Werewolf shall provide Jazz with a copy of all material communications to and from the patent authorities regarding such Licensed Patents, including drafts of any filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow Jazz a reasonable opportunity to review and comment thereon. Werewolf shall consider in good faith Jazz's requests and suggestions with respect to such drafts and with respect to strategies for filing and prosecuting such Licensed Patents. If Werewolf, during the Term, determines in its sole discretion to abandon or not maintain any of such Licensed Patents in the Territory, then Werewolf shall provide Jazz with prior written notice sufficiently in advance of any abandonment to enable Jazz, at its sole discretion, to maintain such Licensed Patents and assume the prosecution, at its sole cost and expense, and on receipt of such notice, Werewolf shall transfer such prosecution to Jazz, provide all relevant documentation and perform all such actions as Jazz may reasonably request to allow a complete and efficient transfer of such Patents.

(b)Jazz Patents. Jazz shall have the sole right, but not the obligation, to prepare, file, prosecute, and maintain the Jazz Background Patents and the Jazz Development Patents worldwide, at Jazz's sole cost and expense. Jazz shall ensure that the Jazz Development Patents do not disclose or claim any Werewolf Development Know-How.

(c)Product Patents. Jazz shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain the Product Patents worldwide, at Jazz's sole cost and expense using patent counsel approved by Werewolf, such approval not to be unreasonably withheld, conditioned or delayed. Jazz shall keep Werewolf fully informed of all steps with regard to the preparation, filing, prosecution, and maintenance of the Product Patents, and shall provide Werewolf with a copy of all material communications to and from the patent authorities regarding the Product Patents, including drafts of any filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow Werewolf a reasonable opportunity to review and comment thereon. Jazz shall consider in good faith Werewolf's requests and suggestions with respect to such drafts and with respect to strategies for filing and prosecuting the Product Patents. Notwithstanding the foregoing, [**]: (i) [**] Product Patent [**]a Product Patent, [**] or (ii) [**] Product Patent [**] Product Patent. If Jazz, during the Term, determines in its sole discretion to abandon or not maintain any of the Product Patents in the Territory, then Jazz shall provide Werewolf with prior written

notice sufficiently in advance of any abandonment to enable Werewolf, at its sole discretion, to maintain such Product Patent and assume the prosecution, at its sole cost and expense, and on receipt of such notice, Jazz shall transfer such prosecution to Werewolf, provide all relevant documentation and perform all such actions as Werewolf may reasonably request to allow a complete and efficient transfer of such Product Patents.

(d) Patent Term Extension. Jazz shall have the sole right to obtain patent term extensions, supplementary protection certificates, and equivalents thereof with respect to any Licensed Product in the Territory, including with respect to any Licensed Patent in any country in the Territory, and Werewolf shall reasonably cooperate with Jazz in connection therewith at Jazz's expense.

13.4 Enforcement of Patents.

(a) Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of any Licensed Patent, or Jazz Development Patent, in any jurisdiction in the Territory of which such Party becomes aware in connection with the Exploitation of any Licensed Product or any product that competes with a Licensed Product (an "**Infringement**").

(b) Werewolf Patents. Werewolf shall have the sole and exclusive right, but not the obligation, to enforce and defend worldwide under its control, at its own expense, the Licensed Patents that are not Product Patents, *provided however*, if (i) [**], (ii) [**], and (iii) [**], Werewolf will agree to enforce, at its sole expense, or to permit Jazz to bring and control any enforcement at Jazz's sole expense, provided that Jazz will allow Werewolf the right to comment on the general legal strategy for such enforcement, and will consider Werewolf's comments in good faith, prior to commencing implementation of such legal strategy.

(c)Jazz Patents. Jazz shall have the sole right, but not the obligation, to enforce and defend worldwide under its control, and at its own expense, the Jazz Background Patents and Jazz Development Patents.

(d) Product Patents.

(i) Jazz shall have the first right, but not the obligation, to enforce and defend worldwide under its control, and at its own expense, all Product Patents. Jazz shall allow Werewolf the right to comment on the general legal strategy to be taken in any such enforcement prior to Jazz commencing implementation of such legal strategy and will advise Werewolf of and allow Werewolf to comment on any material changes to the legal strategy before implementation of such changes.

(ii) If Jazz does not exercise commercially reasonable efforts to enforce or defend any such Infringement with respect to Product Patents (a) within [**] following the first notice provided to it pursuant to this Section 13.4(d), or (b) if earlier, [**] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, then Werewolf may enforce such Product Patents at its own expense.

(e)Cooperation. The Parties agree to cooperate fully in any Infringement action pursuant to this Section 13.4. Where a Party brings such an action, the other Party shall, where necessary, furnish a power of attorney solely for such purpose or shall join in, or be named as a necessary party to, such action. Unless otherwise set forth herein, the Party entitled to bring any Infringement litigation in accordance with this Section 13.4 shall have the right to settle such claim; provided that no Party shall have the right to settle any Infringement litigation under this Section 13.4 in a manner that (a) would restrict the scope or admit the invalidity or unenforceability of a Licensed Patent or Patent controlled by the other Party, (b) diminishes or has a material adverse effect on the rights or interest of the other Party, or (c) imposes any costs or liability on, or involves any admission by, the other Party, in each case (a) – (c) without the express written consent of such other Party, such consent not to be unreasonably withheld, conditioned, or delayed. The Party commencing the litigation shall provide the other Party with copies of all pleadings and other documents filed with the court and shall consider reasonable input from the other Party during the course of the proceedings.

(f) Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described in this Section 13.4 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be treated as follows: (i) to the extent that any award or settlement (whether by judgment or otherwise) is paid to Jazz in respect of any of the Licensed Patents, such amounts shall be [**], and (ii) to the extent that any award or settlement (whether by judgment or otherwise) is paid to Werewolf in respect of any of the Licensed Patents (including Product Patents), such amounts shall be [**].

13.5 Infringement Claims by Third Parties. If the Exploitation of a Licensed Product in the Territory pursuant to this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging patent infringement by Jazz (or its Affiliates or Sublicensees), Jazz shall have the first right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding at its own expense, using counsel of its own choice; *provided*, however, that the provisions of Section 13.4 shall govern the right of Jazz to assert a counterclaim of infringement of any Licensed Patent. Jazz may deduct [**] percent ([**]%) of its total out-of-pocket costs incurred in connection with such action, including reasonable attorneys' fees, damages and other liabilities that are part of any final judgment, and any amounts paid by Jazz in settlement of such action, from the royalties payable to Werewolf under Section 10.4, subject to Section 10.4(d)(iv).

13.6 Invalidity or Unenforceability Defenses or Actions.

(a) Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patents by a Third Party, in each case in the Territory and of which such Party becomes aware.

(b) **Werewolf Patents**. Werewolf shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensed Patents that are not Product Patents. Werewolf shall consult with Jazz to determine a course of action with respect to any proceeding relating to the validity and enforceability of any such Licensed Patent and Werewolf shall consider in good faith any Jazz comments with respect thereto. If Werewolf elects not to defend or control the defense of any such Licensed Patent, or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding, then Jazz may conduct and control the defense of any such claim, suit, or proceeding, at its own expense; *provided* that Jazz shall obtain the written consent of Werewolf prior to settling or compromising such defense, such consent not to be unreasonably withheld, conditioned, or delayed.

(c) **Jazz Patents**. Jazz shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Jazz Background Patents and Jazz Development Patents.

(d) **Product Patents.**

(i) Jazz shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Product Patents. Jazz shall consult with Werewolf regarding its course of action with respect to any proceeding relating to the validity and enforceability of any such Product Patent and Jazz shall consider in good faith any Werewolf comments with respect thereto. Werewolf may participate in any such claim, suit, or proceeding in the Territory related to such Product Patents with counsel of its choice at its own expense; provided that Jazz shall retain control of the defense in such claim, suit, or proceeding. If Jazz elects not to defend or control the defense of any such Product Patents, or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding, then Werewolf may conduct and control the defense of any such claim, suit, or proceeding, at its own expense; *provided* that Werewolf shall obtain the written consent of Jazz prior to settling or compromising such defense, such consent not to be unreasonably withheld, conditioned, or delayed.

(ii) Where Werewolf has assumed the defense of such Product Patent pursuant to Section 13.3(c)(i), Werewolf shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the relevant Product Patents. Jazz may participate in any such claim, suit, or proceeding in the Territory related to such Product Patents with counsel of its choice at its own expense; provided that Werewolf shall retain control of the defense in such claim, suit, or proceeding.

(e) **Cooperation**. Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in this Section 13.6, including by being joined as a party plaintiff in such action or proceeding, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. Each Party shall consult with the other as to the strategy for the defense of the Licensed Patents (including the Product Patents).

13.7 UPC. Jazz will have the right to determine whether to opt in or opt out (and to opt in again) of the Unified Patent Court system with respect of the Product Patents and, if requested by Jazz, Werewolf will promptly do all things reasonably necessary and execute all documents required to give effect to such decision(s), *provided* that Jazz will reimburse Werewolf its reasonable out-of-pocket expenses incurred in performing such acts.

14. Confidentiality

14.1. Confidentiality. All Confidential Information provided by one Party (or its Representatives or Affiliates) (collectively, the "**Disclosing Party**") to the other Party (or its Representatives or Affiliates) (collectively, the "**Receiving Party**") shall be subject to and treated in accordance with the terms of this Section 14.1. "**Confidential Information**" means (a) all information disclosed or made available to the Receiving Party by or on behalf of the Disclosing Party in connection with this Agreement including the negotiation thereof, and (b) all memoranda, notes, analyses, compilations, studies, and other materials prepared by or for the Receiving Party to the extent containing or reflecting the information in the preceding clause (a) or (b), provided that: (i) all Development Records, Information and reports provided by Werewolf pursuant to Article 6 and all Jazz Development Know-How shall be deemed to be Confidential Information of Jazz, and Jazz shall be deemed to be the Disclosing Party and Werewolf the Receiving Party with respect thereto; (ii) the terms of this Agreement and the Licensed Know-How are the Confidential Information of both Parties.

14.2. Exceptions. Notwithstanding the foregoing, the confidentiality obligations of Section 14.1 above shall not include that portion of Disclosing Party's Confidential Information that, in each case as demonstrated by competent written documentation:

(a) was already known to the Receiving Party other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party (but excluding information described in Section 14.1(i) in the case of Werewolf as the Receiving Party);

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party unless such Confidential Information is so available due to the unauthorized actions of the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party other than through any act or omission of the Receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the Receiving Party on a non-confidential basis by a Third Party without obligations of confidentiality with respect thereto; or

(e) is subsequently independently discovered or developed by the Receiving Party without the aid, application, or use of Confidential Information of Disclosing Party.

14.3. Permitted Uses. Commencing on the Effective Date and continuing until [**] after the expiration or termination of this Agreement, (i) Receiving Party may disclose, or permit the disclosure of, any of Disclosing Party's Confidential Information to its Affiliates and their Representatives, provided that such Affiliates and Representatives do not disclose except as

otherwise expressly permitted under this Agreement, or make any unauthorized use of, the Disclosing Party's Confidential Information; (ii) Receiving Party shall treat, and shall cause its Affiliates and the Representatives of Receiving Party or any of its Affiliates to treat, Disclosing Party's Confidential Information as confidential, using the same degree of care as Receiving Party normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or unauthorized disclosure of the Disclosing Party's Confidential Information.

14.4. Authorized Disclosure. Notwithstanding the provisions of Section 14.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) In the case of either Party as the Receiving Party:

(i) enforcing such Party's rights or performing its obligations under this Agreement;

(ii) prosecuting or defending litigation and/or filing for, prosecuting or enforcing Patents as permitted by this Agreement;

(iii) complying with (A) court orders or applicable laws (other than securities laws) or (B) applicable securities laws, or rules of any recognized stock exchange on which the Receiving Party's securities are traded (specifically including the recommendations and requests from the U.S. Securities and Exchange Commission); provided in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to this subparagraph 14.4(a)(iii), it will, except where impracticable, (i) give reasonable advance notice to the Disclosing Party of such disclosure, (ii) use efforts to secure confidential treatment of such information at least as diligent as the Receiving Party would use to protect its own confidential information, and (iii) in the case of disclosures under (A) above, cooperate with any efforts by the Disclosing Party, at the Disclosing Party's request and expense, to prevent or limit disclosure of such Confidential Information;

(iv) disclosure to Third Parties in connection with due diligence or similar investigations, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by obligations of confidentiality and non-use similar to those contained in this Agreement; or

(v) disclosure to a Tax authority in connection with the Tax affairs or a reporting obligation of the Disclosing Party.

(b) In the case of Jazz as the Receiving Party:

(i) in regulatory filings (including for any IND or Drug Approval Application) or otherwise in seeking, obtaining and maintaining Regulatory Approvals (including complying with the requirements of Regulatory Authorities with respect to filing for, obtaining and maintaining such Regulatory Approvals); and

(ii) disclosure to actual or potential Sublicensees, subcontractors, investors, acquirors, or other Third Parties in connection with the exercise of its rights under this Agreement or related activities, or an actual or potential investment, acquisition, license or collaboration, provided, that Jazz uses efforts to secure confidential treatment of such information at least as diligent as the it would use to protect its own confidential information of a similar nature.

14.5 Prior Confidentiality Agreement. This Agreement supersedes the Confidentiality Agreement regarding the subject matter of this Agreement. All information exchanged between the Parties under the Confidentiality Agreement shall be deemed to have been disclosed under this Agreement on a going-forward basis and shall be subject to the terms of Section 14.1 as of the Effective Date. For the avoidance of doubt, the restrictions set forth in Section 3 of Amendment No. 3 shall no longer apply after the Effective Date. However, [**].

14.6 Use of Name. Except as expressly provided in this Agreement, neither Party shall use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance, which approval shall not be unreasonably withheld, conditioned, or delayed. The restrictions imposed by this Section 14.6 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law; provided, that such Party shall submit the proposed disclosure identifying the other Party in writing to such other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment on such disclosure.

14.7 Confidential Disclosure of Terms.

(a) Each Party agrees not to disclose to any Third Party the existence and/or terms of this Agreement without the prior written consent of the other Party hereto, except as permitted under Section 14.2, 14.3 or 14.4 above or Section 14.7(b) below, and notwithstanding the foregoing, each Party may disclose the existence and/or terms of this Agreement to its advisors (including financial advisors, attorneys and accountants), potential and existing investors, collaboration partners or acquirers, and others on a reasonable need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof.

(b) The Parties acknowledge that either or both Parties may be obligated to file under Applicable Law promulgated by Governmental Bodies or applicable securities exchanges a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Bodies. In the event that a Party determines based on advice of outside counsel that such a filing is required, such Party shall request confidential treatment of all Confidential Information herein, including the sensitive commercial, financial, and technical terms hereof, to the extent such confidential treatment may be reasonably available to such Party. In the event of any such filing, the filing Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such filing Party intends to seek confidential treatment within a reasonable amount of time prior to filing and shall use good faith efforts to incorporate the other Party's reasonable comments thereon to the extent consistent with Applicable Law promulgated by Governmental Bodies or applicable securities exchanges. Each Party shall be responsible for its own legal and other external costs in connection with any such filing.

14.8 Public Announcements.

(a) The Parties have mutually approved a press release attached hereto as **Schedule 14.8** with respect to this Agreement. Werewolf agrees not to issue any other press release or other public statement, whether oral or written, disclosing the terms hereof or any of the activities conducted hereunder without the prior written consent of Jazz (such consent not to be unreasonably withheld, conditioned or delayed), except as permitted under Section 14.4(a) above. Notwithstanding the foregoing, after release of a press release in accordance with this Section 14.8(a), Werewolf may disclose to Third Parties the information contained in such press release without further consent.

(b) Jazz shall have the right to issue subsequent press releases or other public statements pertaining to the activities conducted hereunder. For avoidance of doubt, Jazz shall have the right to publicly disclose without Werewolf's prior written consent: (A) the achievement of any milestone under this Agreement; (B) the commencement, completion, material data and key results of any Clinical Trial conducted under this Agreement; and (C) any information relating to the Development or Commercialization of Licensed Compounds and Licensed Products in the Territory.

14.9 Publications. The Parties acknowledge that scientific publications must be strictly monitored to prevent any adverse effect from premature publication of results of the Development activities hereunder.

(a) By Werewolf. Subject to Section 14.4(a) and 14.6, Werewolf shall not have the right or obligation to make any publications, oral presentations, articles, posters, abstracts or other public disclosures related to a Licensed Compound and/or Licensed Product without Jazz's prior written consent.

(b) By Jazz. Subject to Section 14.1, Jazz shall have the right to make any publications, oral presentations, articles, posters, abstracts or other public disclosures related to the Licensed Compound and/or Licensed Product without reference to Werewolf.

14.10 Return of Confidential Information. Upon termination of this Agreement in its entirety, each Party shall promptly return to the other Party, or delete or destroy, all records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations under this Agreement, as required by Applicable Law, or for legal archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

15. Representations and Warranties.

15.1 Due Organization. Each Party represents and warrants as of the Effective Date that:

(a) it is a company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement;

(b) this Agreement has been duly authorized by all necessary corporate action, and do not violate (i) such Party's charter documents, bylaws, or other organizational documents, (ii) any agreement, instrument, or contractual obligation to which such Party is bound, (iii) any requirement of any Applicable Law, or (iv) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party;

(c) it is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent with the terms of this Agreement, or that would impede the diligent and complete fulfilment of its obligations hereunder; and

(d) this Agreement (assuming due authorization, execution and delivery by the other Party) is binding upon it, enforceable against it in accordance with its terms, subject to any applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws now or hereinafter in effect relating to creditors' rights generally or to general principles of equity.

15.2 Intellectual Property. Werewolf represents and warrants to Jazz as follows:

(a) **Schedule 1.126** lists (i) each Licensed Patent existing as of the Effective Date, (ii) the jurisdiction in which such Patents has been registered or filed and the applicable registration or serial number, and (iii) any other Person that has or purports to have an ownership interest in such Patents and the nature of such ownership interest. Werewolf has made available to Jazz copies of all such Licensed Patents and all other material correspondence with any patent office related to each such Licensed Patent.

(b) Other than as disclosed on Schedule 15.2(b), Werewolf is not bound by, and the Licensed Technology (and any part thereof) is not subject to, any agreement containing, any covenant or other provision that in any way limits or restricts the ability of Werewolf or Jazz to Exploit or enforce any Licensed Technology anywhere in the world.

(c) Other than as disclosed on Schedule 15.2(c), Werewolf solely and exclusively owns all right, title, and interest to and in the Licensed Technology free and clear of any encumbrances.

(d) Werewolf (i) does not own or control any Regulatory Approval, and has not submitted to any Regulatory Authority any application for Regulatory Approval, or other regulatory documentation or regulatory filing, in each case for any Licensed Compound or

Licensed Product, and (ii) has not requested or participated in any meeting with any Regulatory Authority or received any correspondence from any Regulatory Authority relating to any such Licensed Compound or Licensed Product.

(e) As of the Effective Date, to Werewolf knowledge, no Person has infringed, misappropriated, or otherwise violated, and no Person is currently infringing, misappropriating, or otherwise violating, any Licensed Technology.

(f) [**], Werewolf has not infringed, misappropriated, or otherwise violated or made unlawful use of the Intellectual Property Rights of any Third Party in the performance of activities related to the Licensed Technology. [**], Werewolf has never received any written notice or other written communication relating to any actual, alleged, or suspected infringement, misappropriation, or violation by Werewolf or any of its Representatives of any Intellectual Property Right of another Person in connection with performance of Development, manufacture or Commercialization of any Licensed Compound or Licensed Product.

(g) With respect to the existing Licensed Patents, and with the exception of proceedings in the relevant patent office in the ordinary course of patent prosecution, no proceeding is pending or is threatened that challenges the validity, enforceability, inventorship, patentability, claim construction, use or ownership of or Werewolf's right to grant a license or other right to the item and, to the knowledge of Werewolf, no valid basis exists for such a challenge.

(h) No funding, facilities, or personnel of any Governmental Body or any university, college, research institute, or other educational institution has been or is being used, directly or indirectly, to create, in whole or in part, Intellectual Property Rights related to the Licensed Technology, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership rights or any other similar right, title or interest (including any "march in" rights) in or to such Intellectual Property Rights (including any claim or option to any of the foregoing).

(i) Werewolf and its Affiliates are, at the Effective Date, in compliance in all respects with the terms of each Werewolf In-License and have performed all obligations required to be performed by Werewolf or its Affiliates pursuant to such agreement in a timely manner. To Werewolf's knowledge, no counterparty to a Werewolf In-License is in breach or default in any respect of a Werewolf In-License and there are no material impediments that would prevent Werewolf or its Affiliates from fulfilling their obligations under each Werewolf In-License.

(j) A true, accurate and complete copy of each Werewolf In-License existing at the Effective Date has been made available to Jazz prior to the Effective Date. Each Werewolf In-License existing at the Effective Date is in force and enforceable according to its terms. Werewolf has not received notice of termination in respect of any Werewolf In-License existing at the Effective Date and is not in discussions or negotiations with respect to any amendment, supplement or other modification (including termination) with respect to any Werewolf In-License.

15.3 Additional Covenants. Werewolf hereby covenants and agrees that:

(a) it shall perform the Werewolf Development Activities in accordance with all Applicable Laws and the generally accepted industry standards of care and diligence practiced by a biopharmaceutical research organization in performing research and development of a similar nature.

(b) it will not employ, contract with, or retain any Person directly or indirectly to perform the Werewolf Development Activities under this Agreement if such Person is presently debarred by a Regulatory Authority, including the FDA pursuant to the Generic Drug Enforcement Act of 1992, as amended (21 U.S.C. § 301, *et seq.*), or it has knowledge that such person is under investigation by a Regulatory Authority for debarment. In addition, Werewolf represents and warrants that to its knowledge, it has not engaged in any conduct or activity that could lead to any such debarment actions. If during the Term, (a) Werewolf or, to its knowledge, any person employed or retained by Werewolf to perform the Werewolf Development Activities comes under investigation by a Regulatory Authority for a debarment action, (b) Werewolf or any person employed or retained by Werewolf to perform the Werewolf Development Activities is debarred, or (c) Werewolf or, to its knowledge, any person employed or retained by Werewolf to perform the Werewolf Development Activities engages in any conduct or activity that could lead to debarment, Werewolf shall immediately notify Jazz of same, and Jazz shall have the right (exercisable within [**] of notice from Werewolf) to terminate this Agreement immediately upon written notice to Werewolf.

(c) It will not, in the course of conducting the Werewolf Development Activities, knowingly after due inquiry (which inquiry obligation shall not require the conduct of a freedom to operate analysis to the extent such analysis has not been previously done) infringe or misappropriate any Intellectual Property Right of any Third Party.

(d) It will ensure that no Werewolf In-License is terminated, revoked or allowed to expire during the Term for any reason attributable to Werewolf or its Affiliates. Notwithstanding the foregoing, Werewolf shall, and shall procure that its Affiliates shall:

(e) not terminate any Werewolf In-License without first obtaining Jazz's express written consent to such termination;

(f) ensure that it complies, at all times, with each of its obligations under each Werewolf In-License in a timely manner;

(g) not agree or consent to any amendment, supplement, or other modification (including termination) to any Werewolf In-License without Jazz's prior written consent;

(h) promptly inform Jazz in the event that Werewolf or any Affiliate of Werewolf receives notice or other communication that any Werewolf In-License may be, or shall be terminated, or Werewolf or any Affiliate of Werewolf otherwise becomes aware that any counterparty to any Werewolf In-License is intending to terminate any Werewolf In-License, for any reason. Without limiting any other right or remedy of Jazz under this Agreement and in order to prevent, ameliorate, mitigate, or cure a breach of any Werewolf In-License by Werewolf

or its Affiliates, in the event that Werewolf fails to perform any of its obligations under any Werewolf In-License, which failure is not cured within [**] after written notice from Jazz, Jazz may, at its sole discretion, perform such obligation on behalf of Werewolf, provided that Jazz shall be entitled to credit any costs, including out-of-pocket and internal costs, against any future payments otherwise owed to Werewolf under this Agreement; and

(i) in the event that any Werewolf In-License terminates or expires, Werewolf shall, if requested by Jazz, use its best efforts to facilitate and assist Jazz and the counterparties to the relevant Werewolf In-License to agree terms on which Jazz may take a direct license to the rights in the Licensed Technology which are sublicensed under such Werewolf In-License to Jazz pursuant to this Agreement.

15.4 Warranty Disclaimer. EXCEPT AS EXPLICITLY SET FORTH IN THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE.

16. Indemnification.

16.1 Indemnification by Werewolf. Werewolf shall hold harmless and indemnify each Jazz Indemnitee for Damages resulting from any claim brought by a Third Party, including a subcontractor (such claim, a "**Third Party Claim**") to the extent arising from:

(a) the Exploitation of any Licensed Technology, Licensed Compound or Licensed Product prior to the Effective Date, including any manufacture of Licensed Compound;

(b) performance of Werewolf's activities under this Agreement, including the Werewolf Development Activities;

(c) the Exploitation of any Licensed Technology on or after the Effective Date other than by Jazz, its Affiliates or Sublicensees;

(d) any breach of any representation or warranty made by, or covenant, or obligation of, Werewolf in this Agreement;

(e) any breach by Werewolf or its Affiliates of an agreement with any subcontractor relating to Werewolf Development Activities;

(f) the negligence or willful misconduct of Werewolf or its Representatives in connection with this Agreement; or

(g) the Exploitation of any Terminated Licensed Product after the effective date of termination of this Agreement with respect thereto;

except in each case to the extent Jazz is obligated to indemnify Werewolf pursuant to Section 16.2 or result from the fault of a Jazz Indemnitee.

16.2 Indemnification by Jazz. Jazz shall hold harmless and indemnify each Werewolf Indemnitee for Damages resulting from any Third Party Claim to the extent arising from:

(a) the Exploitation of any Licensed Compound or Licensed Product by Jazz, its Affiliates and their Sublicensee during the Term, but for the avoidance of doubt, excluding any activities performed by Werewolf under this Agreement, including the Werewolf Development Activities;

(b) any breach of any representation or warranty made by, or covenant, or obligation of, Jazz in this Agreement; or

(c) the negligence or willful misconduct of Jazz or its Representatives in connection with this Agreement;

except in each case to the extent Werewolf is obligated to indemnify Jazz pursuant to Section 16.1 or result from the fault of a Werewolf Indemnitee.

16.3 Indemnification Procedure. A Party that intends to claim indemnification under this Article 16 (the "**Indemnitee**") shall promptly notify the other Party (the "**Indemnitor**") in writing of any Third Party Claim (including a copy of any related complaint, summons, notice or other instrument) for which such Indemnitee intends to base a request for indemnification under Sections 16.1 or 16.2; provided, that failure to give such notification shall not affect the indemnification provided under Sections 16.1 or 16.2 except to the extent the Indemnitor has been actually prejudiced as a result of such failure. Subject to Section 13.5, the Indemnitor shall have the right to control the defense and settlement of such Third Party Claim, at its sole expense, provided (i) the Indemnitor shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the Third Party Claim, (ii) the Indemnitee shall reasonably cooperate in the investigation, defense and settlement of such Third Party Claim at the Indemnitor's expense and (iii) neither Party will enter into any settlement agreement that attributes fault or negligence to the other Party, requires any payment by the other Party, or restricts the future actions or activities of the other Party, without the other Party's prior written consent, which shall not be unreasonably withheld, conditioned or delayed. Any Indemnitee shall have the right to participate in, but not control, the defense and settlement of the Third Party Claim and to employ separate legal counsel of its own choice; provided, however, that such employment shall be at the Indemnitee's own expense, unless (a) the employment thereof has been specifically authorized by the Indemnitor, or (b) the Indemnitor has failed to assume the defense and employ counsel (in which case the Indemnitee shall control the defense and settlement of such Third Party Claim). The reasonable and verifiable costs and expenses, including reasonable fees and disbursements of counsel, incurred by any Indemnitee in connection with any Third Party Claim shall be reimbursed within [**] of each Calendar Quarter by the Indemnitor subject to refund in the event the Indemnitor is ultimately held not to be obligated to indemnify the Indemnitee.

16.4 Exercise of Remedies by Indemnitees Other Than Parties to this Agreement. No Indemnitee (other than the Parties to this Agreement or any successor thereto or permitted assignee thereof) shall be permitted to assert any indemnification claim or exercise any other remedy under this Agreement unless the respective Party to this Agreement entitled to

indemnification (or any successor thereto or permitted assignee thereof) has consented to the assertion of such indemnification claim or the exercise of such other remedy.

16.5 Limitation of Liability. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY NOR ANY OF ITS RESPECTIVE AFFILIATES SHALL BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF) OR ANY RESEARCH PLAN, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, WHETHER OR NOT FORESEEABLE AT THE EFFECTIVE DATE, ARISING. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 16.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 16.1 OR 16.2, AND THE FOREGOING LIMITATIONS SHALL NOT APPLY WITH RESPECT TO DAMAGES RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 14.

17. Term and Termination

17.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Section 17, shall continue in full force and effect on a Licensed Product-by-Licensed Product basis, until the expiration of the last to expire Royalty Term (the "**Term**").

17.2 Termination for Convenience. At any time during the Term, Jazz may terminate this Agreement in its entirety, on a Licensed Product-by-Licensed Product basis, or on a country-by-country basis, for any or no reason, upon [**] prior written notice to Werewolf.

17.3 Termination for Material Breach. Each Party shall have the right to terminate this Agreement in its entirety, or on a Licensed Product-by-Licensed Product or country-by-country basis immediately upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach within [**] after receipt from the non-breaching Party of written notice specifying the breach and requesting its cure; provided that if the breaching Party is Jazz and such material breach relates solely to one (1) or more (but not all) Licensed Products, then Werewolf's right to terminate this Agreement pursuant to this Section 17.3 shall be limited to such Licensed Product(s). If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party, and such alleged breaching Party provides the other Party notice of such dispute within [**], then the other Party shall not have the right to terminate this Agreement under this Section 17.3 unless and until the arbitrator, in accordance with Section 18.3, has determined that the alleged breaching Party has materially breached the Agreement and such Party fails to cure such breach within the applicable cure period set forth above following such decision (or such other cure period specified by the arbitral tribunal).

17.4 Termination for Insolvency. In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property

that is not discharged within [**] after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, or (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [**] of the filing thereof, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party (each, an "**Insolvency Event**").

17.5 Jazz's Alternative Remedy. In the event that Jazz would have the right to terminate this Agreement pursuant to Section 17.3, Jazz may, in its sole discretion, elect to either (a) exercise such termination right, or (b) in lieu of exercising such termination right, and without limiting Jazz's rights otherwise set forth in this Agreement, maintain this Agreement (including the licenses and other rights granted by Werewolf to Jazz under this Agreement) in full force and effect, provided that all future payments owed by Jazz to Werewolf under this Agreement will be reduced by [**] percent ([**]%), provided that under no circumstances shall any of the Development Milestone Payments, Regulatory Milestone Payments or Sales Milestone Payments be reduced by more than [**] percent ([**]%) and Section [**] shall continue to apply. All other terms of this Agreement shall continue to apply.

17.6 Werewolf's Alternative Remedy. In the event that Werewolf would have the right to terminate this Agreement pursuant to Section 17.3 or 17.4, Werewolf may, in its sole discretion, elect to either (a) exercise such termination right, or (b) in lieu of exercising such termination right maintain this Agreement (including the licenses and other rights granted by Werewolf to Jazz under this Agreement) in full force and effect, provided that: (i) [**], and (ii) [**]. All other terms of this Agreement shall continue to apply.

17.7 Effects of Expiration or Termination.

(a) License. Subject to Section 10.4(b), upon termination of this Agreement in its entirety, on a Licensed Product-by-Licensed Product basis or country-by-country basis for any reason, the license and rights granted in Section 3 will terminate with respect to this Agreement or the terminated country or Licensed Product, as applicable.

(b) Sublicensees. If this Agreement terminates for any reason, then upon written notice to Werewolf and at the option of any Sublicensee not in breach of the applicable sublicense (or any provision of this Agreement applicable to such Sublicensee) such Sublicensee will, from the effective date of such termination, automatically become a direct licensee of Werewolf under, and subject to the terms and conditions of, this Agreement, subject only to modifications with respect to territory, field, and exclusivity consistent with the scope of the applicable sublicense and so as to accommodate all such Sublicensees. Such Sublicensees will have the right to grant further sublicenses to Third Parties of same or lesser scope as its sublicense from Jazz under the licenses contained in Section 3, provided that such further sublicenses will be in accordance with and subject to all of the terms and conditions of Section 3.2 (i.e., such Sublicensee shall be subject to this Section 3.2 in the same manner and to the same extent as Jazz). For clarity, any Person to whom a Sublicensee grants a sublicense as permitted by the terms of this Agreement shall be deemed to be a Sublicensee for purposes of this Agreement.

(c) Return of Confidential Information. Upon termination of this Agreement, Receiving Party shall return or destroy all of Disclosing Party's Confidential Information in accordance with Section 14.10.

(d) Payments. Upon termination of this Agreement, Jazz shall reimburse Werewolf for (a) any reasonable, non-cancellable wind-down expenses incurred by Werewolf with respect to Werewolf Development Activities (including payment at the FTE Cost for Werewolf personnel engaged in such wind-down activities) that were in progress as of the effective date of termination and could not be completed prior to the effective date of such termination (except in the event that Jazz has terminated this Agreement pursuant to Sections 17.3 or 17.4) and (b) non-cancellable obligations to Third Parties that were approved in writing by Jazz and incurred by Werewolf in accordance with a Development Plan and Development Budget (except for any non-cancellable obligations to a subcontractor whose breach of this Agreement was the basis for Jazz terminating this Agreement pursuant to Section 17.3). Except as otherwise expressly provided herein, no additional amounts will be payable based on events occurring after the effective date of expiration or termination; provided that the foregoing will not be deemed to limit either Party's indemnification obligations under this Agreement for acts or omissions incurring prior to the effective date of such expiration or termination that are the subject of such indemnification even if the indemnification amount cannot be accrued or determined as of the effective date of such expiration or termination.

(e) [**] Negotiation. Upon termination of this Agreement, except in the event that Jazz has terminated this Agreement pursuant to Sections 17.3 or 17.4, Jazz shall [**] any Licensed Product for which Jazz's rights under this Agreement have been terminated (a "**Terminated Licensed Product**"), and transfer to Werewolf all applicable Regulatory Approvals, INDs and other regulatory materials in each case relating exclusively to the Terminated Licensed Product in the terminated countries, which [**] will require that Werewolf pay Jazz a royalty equal to [**]% of the Net Sales of such Terminated Licensed Product. For the purposes of this Section 17.7(e) ([**] Negotiation), the definitions of "Net Sales" and "Sublicensee" and the terms set forth in Sections 10.4(c) (Royalty Term), 10.4(d)(v) (One Royalty), 10.4(e) (Royalty Reports), 11.1 (Exchange Rate; Manner and Place of Payment), 11.2 (Late Payments), 11.3 (Tax), 12.2 (Financial Records of Jazz; Audits by Werewolf), and 12.3 (Confidential Financial Information) shall apply *mutatis mutandis* to the calculation, payment, recording and auditing of Werewolf's obligations to make royalty payments under this Section 17.7(e) as they applied to Jazz during the Term and, solely for such purpose, each reference in each such Section (and any related definitions) to (A) Jazz will be deemed a reference to Werewolf, (B) Werewolf will be deemed to be a reference of Jazz, and (C) Licensed Product will be deemed to be a reference to Terminated Licensed Product. For clarity, Sections 10.4(d) (Royalty Adjustments) and 13.5 (Infringement Claims by Third Parties) shall not apply to the royalty payments under this Section 17.7(e), which shall not be reduced below [**]% of Net Sales during the applicable Royalty Term. The Parties shall also enter into an agreement, to be negotiated in good faith, and which the Parties have agreed will require that Werewolf pay Jazz a royalty equal to [**]% of the Net Sales of such Terminated Licensed Product, pursuant to which Jazz will (i) grant Werewolf a non-exclusive license, under all [**] Jazz Development Patents which Cover any Terminated Licensed Product, for the sole purpose of Exploiting the Terminated Licensed Product in the terminated countries, and (ii) grant Werewolf a non-exclusive license, under all Jazz Development Know-How which is necessary for or has been

utilized by Jazz in the Exploitation of such Terminated Licensed Product, for the sole purpose of Exploiting the Terminated Licensed Product in the terminated countries.

(f) Development Wind-Down.

(i) With respect to each Clinical Trial that was Initiated by or on behalf of Jazz prior to the termination of this Agreement (whether terminated in its entirety or with respect to the Licensed Product being tested in such Clinical Trial) (an "**Ongoing Clinical Trial**"), if Jazz intends to wind down such Ongoing Clinical Trial, Jazz shall provide a written notice to Werewolf of such intention prior to commencing the wind-down process and shall not commence such wind-down if it receives from Werewolf within [**] of such notice a written request to transition such Ongoing Clinical Trial to Werewolf in accordance with Section 17.7(f)(ii). If Jazz does not receive such a request during such period, then it shall wind down such Ongoing Clinical Trial at its expense.

(ii) In the event Werewolf timely requests transition of any Ongoing Clinical Trial pursuant to Section 17.7(f)(i), then Werewolf will assume responsibility for such Ongoing Clinical Trial, Jazz shall provide reasonable cooperation to Werewolf and its designee(s), at Werewolf's cost and expense, to facilitate, and the Parties shall use reasonable efforts to effect, a reasonable, orderly, and prompt transition of such Ongoing Clinical Trial and transfer of all applicable clinical trial agreements, Regulatory Approvals, INDs and other regulatory materials to Werewolf and/or its designee(s). Any costs, fees and expenses arising from the transfer of any Ongoing Clinical Trials to Werewolf shall be borne: by Werewolf and, to the extent incurred by or on behalf of Jazz, shall be promptly reimbursed by Werewolf.

17.8 Commercial Wind-Down. Jazz, its Affiliates and Sublicensees shall be entitled to continue to sell (but not to actively promote after the effective date of termination) any existing inventory of Licensed Products in respect of which this Agreement has been terminated, in accordance with the terms and conditions of this Agreement, including all payment obligations, for a period of [**] after the effective date of such termination.

17.9 Clinical and Commercial Supplies and Manufacturing.

(a) Clinical Supplies. Upon termination of this Agreement, except in the event that Jazz has terminated this Agreement pursuant to Sections 17.3 or 17.4 and upon Werewolf's request Jazz shall transfer to Werewolf all existing and available inventory of Terminated Licensed Product held by Jazz for Clinical Trials ("**Clinical Material**") and all existing documentation as to the quality of such Clinical Material that is required or reasonably useful for continued or further Clinical Trials and Werewolf shall pay to Jazz an amount equal to the Costs of Goods with respect thereto within [**] of Jazz's invoice therefor. Jazz will disclose to Werewolf any known issues concerning such Clinical Materials that might reasonably subject Werewolf to liability through the use of such Clinical Material, and Werewolf shall have the option to not receive such Clinical Material.

(b) Commercial Supplies. Upon termination of this Agreement, except in the event that Jazz has terminated this Agreement pursuant to Section 17.3 or 17.4 and if a Terminated Licensed Product is being marketed in any terminated country on the effective date of termination, Jazz shall manufacture and supply to Werewolf the marketed Terminated

Licensed Product for a period of up to [**] from the effective date of termination of this Agreement, at a price of [**] percent ([**]%) of the Cost of Goods with respect thereto.

(c) Manufacturing Process Transfer. Jazz shall promptly, at Werewolf's cost and expense, perform technology transfer to transfer the Terminated Licensed Compound and Terminated Licensed Product manufacturing processes to Werewolf, its nominated Affiliate or a Third Party contract manufacturer designated by Werewolf including all Jazz Development Know-How which is necessary or useful to manufacture or have manufactured the Terminated Licensed Compounds and Terminated Licensed Product.

17.10 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that have accrued to the benefit of a Party prior to such termination or expiration. The rights and remedies of the Parties hereto shall be cumulative and not alternative. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, the following Articles and Sections shall survive such termination or expiration: Sections 10.4(c) (last sentence only), 13.2, 15.4, 17.7, 17.8, 17.9, 17.10, and 19.5 through 19.16, and Articles 12, 14, 16, and 18.

18. GOVERNING LAW AND DISPUTE RESOLUTION.

18.1 Governing Law. This Agreement shall be governed in all respects by the laws of the State of New York, without reference to choice of law doctrines or statutes with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law. The United Nations Convention of International Contracts on the Sale of Goods does not apply to this Agreement and is expressly and entirely excluded.

18.2 Resolution by Executive Sponsors. The Parties recognize that disputes as to certain matters may from time to time arise during the term of this Agreement which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 18.2 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement. With respect to all disputes arising between the Parties under this Agreement, including, without limitation, any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within [**] after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executive Sponsors for attempted resolution by good faith negotiations within [**] after such notice is received. If the Executive Sponsors are unable to resolve the dispute, controversy or claim through amicable internal resolution in accordance with this Section 18.2 within [**] after the matter was referred to them and either Party wishes to pursue the matter, such Party may submit such matter for resolution in accordance with Section 18.3.

18.3 Arbitration.

(a) Any dispute that is not resolved pursuant to Section 18.2 shall be finally settled by arbitration in accordance with the then-current rules of the American Arbitration Association (the "**Rules**") by a single arbitrator selected in accordance with the Rules. The seat of arbitration shall be located in New York City, New York, United States. The language to be used in the arbitral proceedings will be English. Any situation not expressly covered by this Agreement shall be decided in accordance with the Rules.

(b) The arbitrator shall issue a reasoned opinion following a full comprehensive hearing, no later than [**] following the selection of the arbitrator as provided for in Section 18.3(a) unless the Parties jointly request an extension or the arbitrator determines in a reasoned decision that the interest of justice or the complexity of the case requires that such limit be extended.

(c) Any award shall be promptly paid in United States Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 18.3(c), and agrees that judgment may be entered in any court of competent jurisdiction and the Parties hereby consent to the jurisdiction of such court for purposes of enforcement of such award.

(d) Each Party shall bear its own legal fees and expenses arising out of the dispute resolution procedures described in this Section 18.3 and shall pay an equal share of the fees and expenses of the arbitrator.

(e) The arbitration proceeding shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Law, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrators, except (i) as required in connection with the enforcement of such award, (ii) as otherwise required by Applicable Law or required of a Party to fulfill a legal duty or protect or pursue a legal right, (iii) with the consent of both Parties, or (iv) where such information is already in the public domain other than as a result of a breach of this clause.

(f) Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief, including specific performance, from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other Intellectual Property Rights, and no such claim shall be subject to arbitration pursuant to this Section 18.3.

18.4 Trial by Jury Waiver. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW THAT CANNOT BE WAIVED, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, AND COVENANTS THAT IT WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY FORUM IN RESPECT OF ANY ISSUE, CLAIM, DEMAND, ACTION OR CAUSE OF ACTION ARISING IN WHOLE OR IN PART UNDER, RELATED TO, BASED ON OR IN CONNECTION WITH THIS AGREEMENT, THE SUBJECT MATTER HEREOF OR ANY AGREEMENT CONTEMPLATED TO BE EXECUTED IN CONNECTION HEREWITH, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER VERBAL OR WRITTEN) OR ACTIONS OF ANY PARTY HERETO IN CONNECTION WITH ANY SUCH AGREEMENTS, WHETHER NOW EXISTING OR HEREAFTER ARISING AND WHETHER SOUNDING IN TORT OR CONTRACT OR OTHERWISE. ANY PARTY HERETO MAY FILE AN ORIGINAL COUNTERPART OR A COPY OF THIS SECTION 18.4 WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF EACH SUCH PARTY TO THE WAIVER OF ITS RIGHT TO TRIAL BY JURY.

19. Miscellaneous Provisions

19.1 [**]. Notwithstanding Section 4.2 above:

(a) in the event of a [**], any product [**], shall not be deemed an Equivalent Product for the purposes of Section 4.2; and

(b) subject to Section 19.1(a) if, after the Effective Date, there is a [**] which results in [**], then if [**], for the period set out in Section 4.2, either:

(i) [**]; or

(ii) institute [**] to ensure that the [**] under this Agreement [**] and that [**], including by [**] and the [**] under this Agreement [**] under this Agreement.

19.2 Rights Upon Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction outside the United States (collectively, the "**Bankruptcy Laws**"), licenses of rights to be "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against Werewolf under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, Werewolf (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by Werewolf. If a case is commenced during the Term by or against Werewolf under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and Jazz elects to retain its rights hereunder as provided in the Bankruptcy Laws, then Werewolf (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to Jazz copies of all information necessary for Jazz to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon Jazz's written request therefor. All rights, powers and remedies of Jazz as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or

hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

19.3 Jazz Affiliates. Without prejudice to the provisions of any Section in this Agreement that explicitly refers to Jazz's Affiliates, the Parties agree that any Affiliates of Jazz may exercise any of the rights granted to Jazz in this Agreement or perform any of Jazz's obligations in this Agreement provided that Jazz shall be responsible for the performance of any of its obligations that are performed by its Affiliates.

19.4 Further Assurances. Each Party shall execute and cause to be delivered to each other Party such instruments and other documents, and shall take such other actions, as such other Party may reasonably request (at or after the Effective Date) and at the sole cost and expense of such other Party, for the purpose of carrying out or evidencing this Agreement.

19.5 Notices. Any notice or other communication required or permitted to be delivered to any Party under this Agreement shall be in writing and shall be deemed delivered, given, and received when delivered (by hand, by international courier or by e-mail (with confirmation of receipt)) to the address or e-mail address set forth beneath the name of such Party below (or to such other address or e-mail address as such Party shall have specified in a written notice given to the other Parties hereto):

if to Werewolf:	Werewolf Therapeutics, Inc. 1030 Massachusetts Avenue, Suite 210 Cambridge, MA 02138 Attn: Legal Department
with a copy (which shall not constitute notice) to:	[**]
if to Jazz:	Jazz Pharmaceuticals Ireland Limited Fifth Floor, Waterloo Exchange Waterloo Road, Dublin 4, Ireland Attention: General Counsel
with a copy (which shall not constitute notice) to:	Jazz Pharmaceuticals, Inc. 3170 Porter Drive Palo Alto, CA 94304 Attention: General Counsel
with a copy (which shall not constitute notice) via electronic mail to:	[**] Attention: Legal Department

19.6 Independent Contractors. Each Party is performing its obligations hereunder as an independent contractor with the full power, authority and responsibility to select the means, methods and manner of its performance. Nothing contained herein will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their

agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

19.7 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that either Party may make such an assignment or transfer without the other Party's consent, but upon written notice to the other Party, to its Affiliate or to the successor to all or substantially all of the business to which this Agreement relates (whether by merger, acquisition, consolidation, sale of assets, sale of a majority of the direct or indirect equity interests in such Party or otherwise). Any permitted assignment shall be binding on the successors, heirs and assigns of the assigning Party. Any assignment or attempted assignment by a Party in violation of the terms of this Section 19.7 shall be null and void.

19.8 Waiver.

(a) No failure on the part of any Person to exercise any power, right, privilege, or remedy under this Agreement, and no delay on the part of any Person in exercising any power, right, privilege, or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege, or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege, or remedy.

(b) No Person shall be deemed to have waived any condition or claim arising out of this Agreement, or any power, right, privilege, or remedy under this Agreement, unless the waiver of such condition, claim, power, right, privilege, or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Person; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

19.9 Amendments. This Agreement may not be amended, modified, altered, or supplemented other than by means of a written instrument duly executed and delivered on behalf of Jazz and Werewolf.

19.10 Severability. In the event that any provision of this Agreement, or the application of such provision to any Person or set of circumstances, shall be determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to Persons or circumstances other than those as to which it is determined to be invalid, unlawful, void, or unenforceable, will not be affected and will continue to be valid and enforceable to the fullest extent permitted by law. In lieu of such invalid, unlawful, void, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such invalid, unlawful, void, or unenforceable provision as may be possible and reasonably acceptable to the Parties.

19.11 Entire Agreement. This Agreement, including all Schedules and attachments hereto, sets forth the entire understanding of the Parties relating to the subject matter thereof and supersede all prior agreements and understandings among or between any of the Parties relating

to the subject matter thereof, including the Confidentiality Agreement. No Party shall be bound by any representation other than as expressly stated in this Agreement.

19.12 Force Majeure. Neither Party shall be liable for any failure to meet its obligations under this Agreement to the extent due to any cause beyond its reasonable control, including acts of God, including hurricanes, floods, epidemics, pandemics, government mandated lockdown or quarantine, and severe weather, strikes or lockouts, labor disputes or shortages, embargoes, acts of terrorism, war, riot, malicious acts or damage, or accidents as a result of any cause beyond its reasonable control (each, a "**Force Majeure Event**"). The affected Party shall promptly notify the other Party of a Force Majeure Event, explaining the nature, details and expected duration thereof. The affected Party shall use commercially reasonable efforts to remedy, remove or mitigate such Force Majeure Event and the effects thereof as soon as practicable. The affected Party shall also keep the other Party reasonably informed as to when it reasonably expects to resume performance in whole or in part of its obligations hereunder and notify the other Party if the cessation of any such Force Majeure Event. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required; provided, however, that in the event the suspension of performance continues for [**] after the date of the initial occurrence of the Force Majeure Event, the Parties shall work in good faith to generate a commercially reasonably plan to resolve such Force Majeure Event within [**] after the date of the initial occurrence of the Force Majeure Event.

19.13 No Third Party Rights. Except for the rights of the Werewolf Indemnitees and Jazz Indemnitees set forth in (and subject to) Article 16, the provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall have any right or claim against either party by reason of these provisions or be entitled to enforce any of these provisions against either Party.

19.14 Headings; Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable and vice versa. The term "including" or "includes" as used in this Agreement means including, without limiting the generality of any description preceding such term, and the word "or" has the inclusive meaning represented by the phrase "and/or." Unless otherwise specified, references in this Agreement to any section shall include all subsections and paragraphs in such Section and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

19.15 English Language. All notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. In the event of any inconsistency or conflict between the English version of this Agreement and any translation of this Agreement into any other language, the English version shall control.

19.16 Counterparts. This Agreement may be executed in counterparts and by electronic (i.e., pdf) or facsimile transmission, each of which shall constitute an original and all of which, when taken together, shall constitute one agreement.

Signature Page Follows

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed and delivered as of the Effective Date.

Jazz Pharmaceuticals Ireland Limited

Signed: /s/ Hugh Kiely

Name: Hugh Kiely

Title: Director

Werewolf Therapeutics, Inc.

Signed: /s/ Dan Hicklin

Name: Dan Hicklin

Title: CEO

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel J. Hicklin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Werewolf Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2022

By: /s/ Daniel J. Hicklin
Daniel J. Hicklin, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy W. Trost, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Werewolf Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2022

By: /s/ Timothy W. Trost
Timothy W. Trost
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

**CERTIFICATIONS OF CEO AND CFO PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Werewolf Therapeutics, Inc. (the "Company") for the period ending March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 10, 2022

By: /s/ Daniel J. Hicklin
Daniel J. Hicklin, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 10, 2022

By: /s/ Timothy W. Trost
Timothy W. Trost
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)